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Interventions for tobacco use cessation in people living with HIV (Review)

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[Intervention Review]

Interventions for tobacco use cessation in people living with HIV

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ABSTRACT

Background

The prevalence of tobacco use among people living with HIV (PLWH) is up to four times higher than in the general population. Unfortunately, tobacco use increases the risk of progression to AIDS and death. Individual- and group-level interventions, and system-change interventions that are effective in helping PLWH stop using tobacco can markedly improve the health and quality of life of this population. However, clear evidence to guide policy and practice is lacking, which hinders the integration of tobacco use cessation interventions into routine HIV care. This is an update of a review that was published in 2016. We include 11 new studies.

Objectives

To assess the benefits, harms and tolerability of interventions for tobacco use cessation among people living with HIV.

To compare the benefits, harms and tolerability of interventions for tobacco use cessation that are tailored to the needs of people living with HIV with that of non-tailored cessation interventions.

Search methods

We searched the Cochrane Tobacco Addiction Group's Specialised Register, CENTRAL, MEDLINE, Embase, and PsycINFO in December 2022.

Selection criteria

We included randomised controlled trials (RCTs) of individual-/group-level behavioural or pharmacological interventions, or both, for tobacco use cessation, delivered directly to PLWH aged 18 years and over, who use tobacco. We also included RCTs, quasi-RCTs, other non-randomised controlled studies (e.g. controlled before and after studies), and interrupted time series studies of system-change interventions for tobacco use cessation among PLWH. For system-change interventions, participants could be PLWH receiving care, or staff working in healthcare settings and providing care to PLWH; but studies where intervention delivery was by research personnel were excluded. For both individual-/group-level interventions, and system-change interventions, any comparator was eligible.

Data collection and analysis

We followed standard Cochrane methods, and used GRADE to assess certainty of the evidence. The primary measure of benefit was tobacco use cessation at a minimum of six months. Primary measures for harm were adverse events (AEs) and serious adverse events (SAEs). We

also measured quit attempts or quit episodes, the receipt of a tobacco use cessation intervention, quality of life, HIV viral load, CD4 count, and the incidence of opportunistic infections.

Main results

We identified 17 studies (16 RCTs and one non-randomised study) with a total of 9959 participants; 11 studies are new to this update. Nine studies contributed to meta-analyses (2741 participants).

Fifteen studies evaluated individual-/group-level interventions, and two evaluated system-change interventions. Twelve studies were from the USA, two from Switzerland, and there were single studies for France, Russia and South Africa. All studies focused on cigarette smoking cessation. All studies received funding from independent national- or institutional-level funding. Three studies received study medication free of charge from a pharmaceutical company. Of the 16 RCTs, three were at low risk of bias overall, five were at high risk, and eight were at unclear risk.

Behavioural support or system-change interventions versus no or less intensive behavioural support

Low-certainty evidence (7 studies, 2314 participants) did not demonstrate a clear benefit for tobacco use cessation rates in PLWH randomised to receive behavioural support compared with brief advice or no intervention: risk ratio (RR) 1.11, 95% confidence interval (CI) 0.87 to 1.42, with no evidence of heterogeneity. Abstinence at six months or more was 10% (n = 108/1121) in the control group and 11% (n = 127/1193) in the intervention group. There was no evidence of an effect on tobacco use cessation on system-change interventions: calling the quitline and transferring the call to the patient whilst they are still in hospital ('warm handoff') versus fax referral (RR 3.18, 95% CI 0.76 to 13.99; 1 study, 25 participants; very low-certainty evidence).

None of the studies in this comparison assessed SAE.

Pharmacological interventions versus placebo, no intervention, or another pharmacotherapy

Moderate-certainty evidence (2 studies, 427 participants) suggested that varenicline may help more PLWH to quit smoking than placebo (RR 1.95, 95% CI 1.05 to 3.62) with no evidence of heterogeneity. Abstinence at six months or more was 7% (n = 14/215) in the placebo control group and 13% (n = 27/212) in the varenicline group. There was no evidence of intervention effects from individual studies on behavioural support plus nicotine replacement therapy (NRT) versus brief advice (RR 8.00, 95% CI 0.51 to 126.67; 15 participants; very low-certainty evidence), behavioural support plus NRT versus behavioural support alone (RR 1.47, 95% CI 0.92 to 2.36; 560 participants; low-certainty evidence), varenicline versus NRT (RR 0.93, 95% CI 0.48 to 1.83; 200 participants; very low-certainty evidence), and cytisine versus NRT (RR 1.18, 95% CI 0.66 to 2.11; 200 participants; very low-certainty evidence).

Low-certainty evidence (2 studies, 427 participants) did not detect a difference between varenicline and placebo in the proportion of participants experiencing SAEs (8% (n = 17/212) versus 7% (n = 15/215), respectively; RR 1.14, 95% CI 0.58 to 2.22) with no evidence of heterogeneity. Low-certainty evidence from one study indicated similar SAE rates between behavioural support plus NRT and behavioural support only (1.8% (n = 5/279) versus 1.4% (n = 4/281), respectively; RR 1.26, 95% CI 0.34 to 4.64). No studies assessed SAEs for the following: behavioural support plus NRT versus brief advice; varenicline versus NRT and cytisine versus NRT.

Authors' conclusions

There is no clear evidence to support or refute the use of behavioural support over brief advice, one type of behavioural support over another, behavioural support plus NRT over behavioural support alone or brief advice, varenicline over NRT, or cytisine over NRT for tobacco use cessation for six months or more among PLWH. Nor is there clear evidence to support or refute the use of system-change interventions such as warm handoff over fax referral, to increase tobacco use cessation or receipt of cessation interventions among PLWH who use tobacco. However, the results must be considered in the context of the small number of studies included. Varenicline likely helps PLWH to quit smoking for six months or more compared to control. We did not find evidence of difference in SAE rates between varenicline and placebo, although the certainty of the evidence is low.

PLAIN LANGUAGE SUMMARY

How effective are different ways to help people living with HIV stop using tobacco, and do they cause unwanted effects?

Key messages

• Varenicline (a medicine that decreases nicotine cravings) when compared to placebo (dummy pill), likely helps people living with HIV who smoke tobacco to stop smoking for six months or more, and may not increase the chances of experiencing serious unwanted effects.

• We don't know if other methods that are used to help people stop using tobacco can help people living with HIV to quit for six months or more because we did not find enough information.

• Future studies should be bigger and provide information on serious unwanted events.

Why is tobacco use among people living with HIV a problem?

Many people living with HIV worldwide use tobacco, that is, the tobacco plant leaf and its products, for example through smoking, chewing, sucking or sniffing. Tobacco use causes a range of health problems and many deaths, but people become addicted to nicotine in tobacco, and find it difficult to quit. Smoking rates are about four times higher in people living with HIV than in the general population. Unfortunately, even with access to effective HIV treatment, people living with HIV can lose about 12 years of their life because of smoking - more than double the number of years that they are likely to lose because of HIV infection on its own.

How can people living with HIV stop using tobacco?

Methods that are used to help people stop using tobacco include medicines such as nicotine replacement therapy (NRT), varenicline and cytisine (medicines that decrease nicotine cravings) and bupropion (an antidepressant). Other methods include behavioural therapies such as information on the risks of smoking (brief advice), or individual or group counselling (behavioural support). Some health services try changing the way they deliver care (system change). It is unclear whether these interventions can help people living with HIV quit tobacco use.

What did we want to find out?

We wanted to find the best methods to help people living with HIV stop using tobacco, and see whether there were unwanted effects.

What did we do?

We searched for studies that investigated quit methods aimed directly at adults with diagnosed HIV. Also, studies on system change, aimed at people living with HIV who were receiving care, or healthcare staff working in these facilities. Studies could compare quit methods with a placebo (dummy) or no treatment, or another method. We only included studies that examined quitting tobacco for six months or longer. Ideally, quitting had to be verified with a chemical test. We also wanted to find out if the quit methods caused serious unwanted effects.

We compared and summarised the results of the studies and rated our confidence in the evidence, based on factors such as study methods and sizes.

What did we find?

We found 17 studies with 9959 people. Twelve studies were in the USA. Fifteen studies investigated quitting smoking, either with individuals or groups. Two studies evaluated changes in the way care was delivered to people living with HIV attending a health facility.

Behavioural support or system-change compared with no behavioural support or less intensive behavioural support
• There was no clear evidence that behavioural support was more effective for quitting tobacco than brief advice or no support (7 studies, 2314 people).

• Changing the quitline process from referring a patient to a quitline by fax to calling the quitline and transferring the call to the patient whilst they are still in hospital did not show clear evidence of better quit rates (1 study, 25 people).

• None of the studies in this comparison assessed serious unwanted effects.

Medications for quitting tobacco compared with placebo, no medication or another type of medication
• Varenicline likely helps people living with HIV to quit smoking compared to placebo (2 studies, 427 participants).

• Single studies looked at behavioural support plus NRT compared with brief advice, behavioural support plus NRT compared with behavioural support alone, varenicline compared with NRT, and cytisine compared with NRT. The evidence did not show that any of these methods helped people to stop using tobacco.

• There are probably no more unwanted effects with varenicline than placebo (2 studies, 427 participants). There may be no difference in the proportion of people who experience serious unwanted effects between behavioural support plus NRT and behavioural support only (1 study, 560 people). No studies assessed serious unwanted effects for behavioural support plus NRT compared with brief advice, varenicline compared with NRT, and cytisine compared with NRT.

What are the limitations of the evidence?

Our overall confidence in the evidence is moderate to very low, mainly because there were not enough studies to be certain about the results, and sometimes we did not have all the information we needed to evaluate the quality of the studies.

How up to date is this evidence?

This review updates our previous review. The evidence is up to date until December 2022.

SUMMARY OF FINDINGS

Summary of findings 1. Behavioural support or system change interventions compared with no or less intensive behavioural support for tobacco use cessation in people living with HIV

Behavioural support or system-change interventions for tobacco use cessation in people living with HIV

Patient or population: adults (18 + years) living with HIV who use tobacco

Settings: clinical settings (e.g. HIV clinics, outpatient clinics, hospitals, etc.) or the community

Intervention: behavioural support (e.g. cessation counselling) or system-change intervention

Comparison: no intervention, or less intensive behavioural support

Comparison	Outcome	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
		Assumed risk	Risk with intervention				
Behavioural support versus brief advice or no intervention	Tobacco use cessation at 6 + months' follow-up (using strictest measure available[a])	96 per 1000	**107 per 1000** (84 to 137)	**RR 1.11** (0.87 to 1.42)	2314 (7 studies)	⊕⊕⊖⊖ **Low[b,c]**	-
	Serious adverse events (self-report)	No data	No data	No data	No data	No data	-
System-change interventions: 'warm handoff' versus fax referral	Tobacco use cessation at 6 + months' follow-up (using strictest measure available[a])	143 per 1000	**454 per 1000** (109 to 1000)	**RR 3.18** (0.76 to 13.39)	25 (1 study)	⊕⊖⊖⊖ **Very low[c,d]**	-
	Serious adverse events (self-report)	No data	No data	No data	No data	No data	-

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Abstinence measured at longest follow-up, favouring prolonged or continuous abstinence over point prevalence, and where available, using biochemically validated rather than self-reported abstinence.
[b]While there was some heterogeneity in whether counselling was provided in conjunction with pharmacotherapy, we did not downgrade because statistical heterogeneity was low and there was no evidence of subgroup difference.
[c]Downgraded two levels for imprecision: confidence interval incorporates clinically significant benefit as well as clinically significant harm.
[d]Downgraded one level because of risk of bias; sole study in analysis judged to be at high risk.

Summary of findings 2. Pharmacological interventions compared with placebo, no intervention, or another pharmacotherapy for tobacco use cessation in people living with HIV

Pharmacological interventions for tobacco use cessation in people living with HIV

Patient or population: adults (18 + years) living with HIV who use tobacco

Settings: clinical settings (e.g. HIV clinics, outpatient clinics, hospitals, etc.) or the community

Intervention: pharmacotherapy (i.e. nicotine replacement therapy (NRT), bupropion, varenicline, or cytisine)

Comparison: placebo, no intervention, or another pharmacotherapy

Comparison	Outcome	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
		Assumed risk	Risk with intervention				
Behavioural support + NRT versus brief advice	Tobacco use cessation at 6 + months' follow-up (using strictest measure available[a])	0 out of 7	4 out of 8	**RR 8.00** (0.51 to 126.67)	15 (1 study)	⊕⊖⊖⊖ **Very low[b,c]**	
	Serious adverse events (self-report)	No data	No data	No data	No data	No data	-
Behavioural support + NRT versus behavioural support alone	Tobacco use cessation at 6 + months' follow-up (using strictest measure available[a])	93 per 1000	**136 per 1000** (85 to 218)	**RR 1.47** (0.92 to 2.36)	560 (1 study)	⊕⊕⊖⊖ **Low[b]**	-
	Serious adverse events (self-report)	14 per 1000	**18 per 1000** (5 to 66)	**RR 1.26** (0.34 to 4.64)	560 (1 study)	⊕⊕⊖⊖ **Low[b]**	-
Varenicline versus placebo	Tobacco use cessation at 6 + months' follow-up (using strictest measure available[a])	65 per 1000	**128 per 1000** (69 to 236)	**RR 1.95** (1.05 to 3.62)	427 (2 studies)	⊕⊕⊕⊖ **Moderate[d]**	-

	Serious adverse events (self-report)	70 per 1000	**80 per 1000** (40 to 155)	**RR 1.14** (0.58 to 2.22)	427 (2 studies)	⊕⊕⊖⊖ **Low**[b]	-
Varenicline vs NRT	Tobacco use cessation at 6 + months' follow-up (using strictest measure available[a])	150 per 1000	**140 per 1000** (72 to 275)	**RR 0.93** (0.48 to 1.83)	200 (1 study)	⊕⊖⊖⊖ **Very low**[b,c]	-
	Serious adverse events (self-report)	No data	No data	No data	No data	No data	-
Cytisine vs NRT	Tobacco use cessation at 6 + months' follow-up (using strictest measure available[a])	170 per 1000	**201 per 1000** (112 to 359)	**RR 1.18** (0.66 to 2.11)	200 (1 study)	⊕⊖⊖⊖ **Very low**[b,c]	-
	Serious adverse events (self-report)	No data	No data	No data	No data	No data	-

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **NRT:** nicotine replacement therapy; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a]Abstinence measured at longest follow-up, favouring prolonged or continuous abstinence over point prevalence, and where available, using biochemically validated rather than self-reported abstinence.
[b]Downgraded two levels for imprecision: confidence interval incorporates clinically significant benefit as well as clinically significant harm.
[c]Downgraded one level because of risk of bias; sole study in analysis judged to be at high risk.
[d]Downgraded one level for imprecision: confidence interval incorporates no clinical difference as well as clinically significant harm.

BACKGROUND

Description of the condition

HIV is an infection that attacks and destroys the body's immune system, particularly the CD4 cells (a class of T lymphocyte; LEVY 1989). Untreated HIV infection leads to the gradual depletion of CD4 cells, resulting in increased vulnerability to opportunistic infections and other complications (Naif 2013). Treatment with antiretroviral therapy (ART) aims to achieve viral suppression, that is, to reduce the amount of HIV virus in the blood (the 'viral load') to an undetectable level, and increase the CD4 cell count. The introduction of combination ART and other improvements in health care for people living with HIV (PLWH) have resulted in a markedly improved prognosis, with life expectancy nearly approaching that seen in the general population (Kaplan 2009; Marcus 2020; The D:A:D Study Group 2008). Global HIV-related mortality peaked in 2005, at approximately 1.8 million. Since then, there has been a steady decline of approximately 5.5% per year to approximately 680,000 HIV-related deaths globally in 2020 (World Health Organization 2021). Among PLWH, the percentage of all deaths that are AIDS-related has decreased substantially; for example, from 34% in 1999 to 2000, to 22% in 2009 to 2011 (Smith 2014). Because of the rapidly changing landscape of HIV disease prevention and treatment, HIV/AIDS care has shifted from treating a usually fatal infection to managing a chronic condition (Harripersaud 2017). Non-AIDS-related causes of morbidity and mortality, such as cancer, have become important among PLWH.

The prevalence of tobacco use in PLWH varies from country to country but is generally substantially higher than in the general population. For example, a secondary analysis of nationally representative data from 28 low- and middle-income countries (LMICs) found the prevalence of tobacco use to be 1.4 times higher among both men and women living with HIV, than their HIV-negative counterparts (Mdege 2017). The prevalence of current smoking was one and a half times higher in men living with HIV than HIV-negative men, and almost two-fold in women living with HIV than HIV-negative women; and that of smokeless tobacco use was 1.3 times higher among both men and women living with HIV, than their HIV-negative counterparts (Mdege 2017). For the USA, for example, it is estimated that 40% to 70% of PLWH smoke, which is two to four times higher than the percentage of smokers in the general US population (Jamal 2014; Mdodo 2015; Pacek 2014; Vijayaraghavan 2014). Unfortunately, for PLWH, tobacco use, particularly smoking, has been found to impair T-cell immune activation and function, and combined with HIV infection, this leads to an extremely deficient immune system, thus increasing the risk of acquiring infections such as tuberculosis, a key cause of death among PLWH (Bronner 2016). It also increases the risk of progressing to AIDS (Feldman 2006). Studies have shown that, compared to non-smokers, smokers who initiate ART have a lower chance of achieving a viral or immunologic response and a greater chance of developing viral or immunologic failure (Miguez-Burbano 2003). In addition, smoking increases PLWH's risk of non-adherence to ART (Moreno 2015; Nguyen 2016), and non-AIDS related diseases such as chronic lung disease, lung cancer and cardiovascular diseases (CVD). The risk of non-AIDS-related death in PLWH who smoke is at least fivefold that among PLWH who do not smoke (Petoumenos 2011; Soliman 2015; Wistuba 1998). Where ART is accessible, PLWH who smoke lose 12.3 life years to smoking: more than twice the number of years lost to HIV infection alone (Helleberg 2013). Hence, tobacco use cessation can significantly decrease the risk of multimorbidity and the associated mortality among PLWH, and can result in significant health and economic gains (Helleberg 2013).

Among PLWH, smoking cessation has the potential to decrease all-cause mortality by as much as 16%, and also decrease the incidence of CVD events, non-AIDS-related cancers and bacterial pneumonia by as much as 17%, 34% and 18%, respectively (Lifson 2010). Unfortunately, studies show that PLWH who use tobacco are less likely to quit compared to the general population (Mdodo 2015). This is, in part, because of a higher prevalence of co-consumption of other psychoactive substances (alcohol and illicit drugs) and a higher nicotine dependency level, which, in turn, renders them more susceptible to withdrawal symptoms (Zyambo 2019). Other obstacles to tobacco use cessation among PLWH include a sense of fatalism, the use of tobacco to cope with physical comorbidities and stigma, low employment, and low educational attainment (Humfleet 2009; Tesoriero 2010). Mental health problems are also highly prevalent among PLWH and are associated with higher rates of tobacco use and relapse among those attempting to quit (Fond 2013). In addition, a high percentage of PLWH social networks that play a key role in HIV disease management and support are tobacco users themselves, hindering tobacco use cessation efforts for PLWH catered for by these networks (Humfleet 2009).

Description of the intervention

In the general population, there are a range of effective tobacco use cessation interventions (Livingstone-Banks 2022; Rigotti 2022), often delivered in healthcare settings (Carson-Chahhoud 2019; Clair 2019; Holliday 2021; Rice 2017; Rigotti 2012). Tobacco use cessation interventions may be brief advice (Stead 2013), behavioural (Hartmann-Boyce 2021), pharmacological (Lindson 2023), or a combination (Hartmann-Boyce 2018; Stead 2016). Brief advice comprises giving information on the risks of tobacco use and the benefits of quitting in a few minutes during a routine consultation or interaction with a physician or healthcare worker (World Health Organization 2019). On the other hand, behavioural-support interventions may include group or individual counselling consisting of appointments following the quit attempt where the tobacco users receive information, advice, and encouragement (Lancaster 2017; Stead 2017). This can be delivered face-to-face, over the telephone or by video call (Matkin 2019; Tzelepis 2019). Behavioural support can also be delivered in the form of SMS messages, and computer- or smart phone-based applications (Taylor 2017; Whittaker 2019), or via printed self-help materials (Livingstone-Banks 2019a). Pharmacological interventions may include the use of nicotine replacement therapy (NRT) via a range of modalities, as well as bupropion, cytisine or varenicline (Hajizadeh 2023; Hartmann-Boyce 2018; Lindson 2023; Livingstone-Banks 2023; Theodoulou 2023). In some countries, the use of nicotine-containing electronic cigarettes (e-cigarettes) to support tobacco use cessation is also recommended (Lindson 2023). The literature on tobacco use cessation suggests that individual pharmacotherapies are effective for tobacco use cessation; however, these are found to be more effective in the general population when used in combination with behavioural support (Hartmann-Boyce 2021; Stead 2016).

Tobacco use cessation interventions may also be system-change interventions, that is, specific policy and practice strategies that organisations can implement to integrate the systematic

identification of tobacco users along with a subsequent offering of evidence-based cessation treatments into usual care (Agency for Healthcare Research and Quality 2008; Fiore 2007). They include the following (Fiore 2007).

- Implementation of a system for identifying tobacco users and documenting tobacco use status in every clinic and hospital
- Provision of education, resources, and feedback to promote provider interventions
- Provision of dedicated staff for the delivery of tobacco use cessation interventions, and assessing the delivery in staff performance evaluations
- Promotion of clinic or hospital policies, or both, that support and provide tobacco use cessation services
- Provision of evidence-based tobacco dependence treatments (both counselling and pharmacotherapy)
- Reimbursement of providers for the delivery of effective tobacco dependence treatments and inclusion of these services among their defined duties

How the intervention might work

Tobacco contains nicotine, a highly addictive substance that acts by activating some nicotinic receptors in the brain to release dopamine. When a person quits tobacco use, they can experience craving and withdrawal symptoms, which makes it difficult to sustain tobacco abstinence and results in early relapse (Lindson 2023). NRT helps reduce craving and withdrawal by replacing the nicotine from tobacco (World Health Organization 2019). NRT delivers a low and controlled dose of nicotine slowly through the skin when transdermal patches are used, or fast through the oral mucosa (using chewing gum, lozenges, sublingual tablets, inhaler/inhalator, mouth spray and strips, etc.) or nasal mucosa (using sprays). NRT can be stopped after some weeks, when the urges to use tobacco subside, without resulting in withdrawal symptoms in most people (World Health Organization 2019). Nicotine-containing e-cigarettes function in a similar way to NRT. In some countries, e-cigarettes are considered to be the same as tobacco products. However, for this review, we do not consider e-cigarettes to be the same as tobacco products, as they do not contain any tobacco constituent apart from nicotine (Lindson 2023). Currently, available evidence suggests that they are effective cessation aids (Lindson 2023).

Varenicline and cytisine, which are nicotine receptor partial agonists, both work by activating the nicotinic receptors in the brain, thereby preventing nicotine's action on these receptors (Lindson 2023). This reduces craving and withdrawal symptoms as well as the pleasurable effects of tobacco products (World Health Organization 2019).

Bupropion, an antidepressant, is licenced as a tobacco use cessation pharmacotherapy in many countries (World Health Organization 2019). It is not clear how bupropion works as a tobacco use cessation aid. It is possible that its effects might be on neural pathways or receptors that underlie nicotine addiction, or through relieving depressive symptoms that might arise from nicotine withdrawal (Hajizadeh 2023; Lindson 2023).

System-change tobacco use cessation interventions work by improving process outcomes such as documentation of smoking status, provision of cessation counselling and referral to tobacco use cessation services (Thomas 2017).

Why it is important to do this review

Tobacco use cessation interventions that are effective in helping PLWH stop using tobacco can markedly improve the health and quality of life of this population. PLWH who are engaged in care come into frequent contact with health professionals for regular tests and clinic appointments. This presents an opportunity to discuss and support tobacco use cessation, but currently, this opportunity is underutilised. Studies have shown that positive tobacco use cessation-related interactions with HIV care providers increase the likelihood of interest in cessation among HIV-positive tobacco users (Pacek 2017). A substantial proportion of PLWH who use tobacco express a desire to quit, and remain motivated to quit even after experiencing unsuccessful quit attempts (Benard 2007; Shuter 2012a). HIV clinicians recognise the importance of tobacco use cessation among PLWH. However, they face a number of barriers that prevent them from providing tobacco use cessation interventions, including a lack of confidence in initiating cessation therapies and insufficient time (Horvath 2012; Shuter 2012b). In addition, the lack of clear evidence to guide policy and practice in this area also hinders the integration of tobacco use cessation interventions into routine HIV care.

This is an update of a Cochrane review of interventions for tobacco use cessation in PLWH first published in 2016 (Pool 2016). The previous Cochrane review concluded that intensive interventions combining behavioural support (e.g. counselling) and pharmacotherapy were effective in helping PLWH to stop smoking but only in the short term (< 6 months; Pool 2016). However, long-term effects are more useful for policy and practice decision-making. Since the previous review, several new studies investigating tobacco use cessation interventions among PLWH have been published (Ashare 2019; Gryaznov 2020; Kim 2018; Stanton 2020). In addition to individual-/group-level interventions delivered directly to PLWH who use tobacco, studies have also investigated system-change interventions. We will, therefore, update the previous review in two ways:

1. focusing on outcomes measured at six months or longer; and
2. assessing the effectiveness of system-change interventions that aim to improve tobacco use cessation provision for PLWH, in addition to individual-/group-level interventions delivered directly to PLWH who use tobacco.

The work was guided by the previously published review protocol (Pool 2014).

OBJECTIVES

Primary objective

To assess the benefits, harms and tolerability of interventions for tobacco use cessation among people living with HIV.

Secondary objective

To compare the benefits, harms and tolerability of interventions for tobacco use cessation that are tailored to the needs of people living with HIV with that of non-tailored cessation interventions.

METHODS

Criteria for considering studies for this review

Types of studies

For studies on individual-/group-level interventions delivered directly to PLWH who use tobacco, we included randomised controlled trials (RCTs) in the review.

For studies on system-change interventions, in addition to RCTs, we also included quasi-RCTs, other non-randomised controlled studies (e.g. controlled before and after studies), and interrupted time series (ITS) studies, provided they had a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention. We considered quasi-RCTs to be those where allocation of participants to the intervention and control groups was not truly random; for example, based on date of birth, day of the week, or according to the order in which they arrive at the clinics (Torgerson 2008).

We excluded cross-over studies because of the types of interventions used, outcomes investigated and the possibility of problematic carry-over effects.

We did not exclude studies on the basis of language or publication status.

Types of participants

For individual-/group-level interventions delivered directly to PLWH who use tobacco, we included studies if they enroled participants who were adults aged 18 years and older, who had diagnosed HIV. We included participants with all stages of HIV infection. Study participants were current users of tobacco, as defined by the individual studies. Studies with only a subset of eligible participants were incorporated into the review only if all relevant data from the eligible participants could be retrieved. We excluded studies of former tobacco users as these are covered in a separate Cochrane review (Livingstone-Banks 2019b).

For system-change interventions, eligible studies were those testing interventions or healthcare systems, or both, designed to improve tobacco cessation treatment for PLWH. Therefore, recruited participants could be the PLWH receiving care, or the staff working in healthcare settings and providing care to PLWH, evaluating the system-change intervention.

Types of interventions

We included any tobacco use cessation intervention that targeted PLWH, as well as system-change interventions for tobacco use cessation among PLWH.

Individual-/group-level interventions could be non-pharmacological (e.g. behavioural), pharmacological, or a combination of the two types. Pharmacological interventions could include the use of NRT, bupropion, cytisine and varenicline. We also included trials of e-cigarettes as cessation aids, as well as tobacco use cessation induction trials that aim to encourage future quit attempts by tobacco users who were unwilling to give up at the time of recruitment (typically brief advice by health professionals). There was no restriction on the delivery method of the intervention, such as telephone call, mobile text, via the internet or face-to-face interaction; or the status of the person delivering the intervention, which could include doctors, nurses, counsellors, other health workers, lay health workers or peers.

For system-change interventions, we included interventions that had been developed for identifying people who use tobacco, documenting tobacco use status and providing tobacco dependence treatment, pharmacological or non-pharmacological, or both, for PLWH. We excluded studies of interventions with research personnel involvement in intervention delivery as these are not consistent with integration in routine care.

Comparator

We included studies that compared tobacco use cessation interventions with any comparator, including but not limited to no intervention, wait-list controls, usual care, or other active interventions such as those described above.

Types of outcome measures

Primary outcomes

Primary measure of benefit

- Tobacco use cessation at a minimum of six months after the start of the intervention, referred to as long-term cessation. Measurement of cessation at six months or longer is optimal (West 2005). We, therefore, excluded studies with a shorter follow-up. We used the strictest criteria to define cessation available in each study, and therefore included both continuous or prolonged abstinence (defined as abstinence between quit day or predetermined grace period and a follow-up time) and point prevalence abstinence (defined as the prevalence of abstinence during a time window immediately preceding the follow-up). Where both were reported, we preferred continuous or prolonged abstinence over point prevalence abstinence. Where both biochemically verified and self-reported abstinence were reported, we preferred biochemically verified over self-report. These outcome measures are guided by the Russell Standard for tobacco use cessation studies (West 2005).

Primary measure of harm

- Number of participants reporting adverse events (AEs) between baseline and the last follow-up. AEs are commonly defined as any untoward and unintended response to an intervention (Peryer 2023). For brief advice and behavioural support, for example, the information provided might cause anxiety and distress for some participants. Tobacco use cessation pharmacotherapies, including NRT, bupropion, cytisine and varenicline can result in untoward effects such as gastrointestinal problems, cardiovascular problems and headaches. In addition, bupropion can cause mood changes and appetite changes, whilst varenicline has a potential to cause psychiatric disorders such as episodes of depression.
- Number of participants reporting serious adverse events (SAEs) between baseline and the last follow-up. SAEs are commonly defined as events that result in death, are life-threatening, require or prolong hospitalisation, result in persistent or significant disability or incapacity, or a combination of these.

We included a study if it reported any of the primary outcomes at follow-up of six months or longer.

Secondary outcomes

Secondary outcomes were as follows.

- Quit attempts or quit episodes, defined as a period of intentional abstinence lasting for at least 24 hours (Piper 2020)
- The proportion of participants who are tobacco users at the time of a consultation who receive a tobacco use cessation intervention (Edelman 2020; Kastaun 2020)
- Quality of life, measured using health-related quality of life measures such as the WHO Quality of Life Assessment (World Health Organization 1995), EQ-5D (Hurst 1997), and SF-36 (Lins 2016)
- HIV viral load
- CD4 count
- The incidence of opportunistic infections

The time point for secondary outcomes was at follow-up of six months or longer.

Search methods for identification of studies

Electronic searches

We searched the databases listed below on 01 December 2022. All searches cover a period from database inception to our search date.

- Cochrane Tobacco Addiction Group's Specialised Register (via CRS-Web; for details of how this register is populated, see the Cochrane Tobacco Addiction Group's website: tobacco.cochrane.org/resources/cochrane-tag-specialised-register.)
- Cochrane Central Register of Controlled Trials (CENTRAL; 2022, Issue 11) via CRS Web
- MEDLINE Ovid (1946 to 01 December 2022)
- Embase Ovid (1974 to 01 December 2022)
- PsycINFO Ovid (1967 to 01 December 2022)

By searching CENTRAL, we were able to identify studies registered in the World Health Organization's International Clinical Trials Registry Platform (ICTRP) (www.who.int/trialsearch) and US National Library of Medicine's ClinicalTrials.gov. At the time of the search, the Register included the results of searches of MEDLINE (via OVID) to update 10 November 2022; Embase (via OVID) to week 05 April 2022; PsycINFO (via OVID) to update 31 October 2022.

For our full search strategies for the Cochrane Tobacco Addiction Group's Specialised Register, CENTRAL, MEDLINE, PsycINFO and Embase, please see Appendix 1.

We did not impose any restrictions on the searches.

Searching other resources

We reviewed reference lists of literature reviews on tobacco use cessation interventions among PLWH (Keith 2016; Ledgerwood 2016; Moscou-Jackson 2014), and consulted investigators working on the topic via email. We also contacted investigators of ongoing studies that appeared to be complete, but for which the results were not yet published.

Data collection and analysis

Selection of studies

Two review authors (from NDM, SS, OD and JLB) independently screened each study for eligibility using a standardised, pilot-tested study selection form based on the prespecified study eligibility criteria. The first stage involved screening titles and abstracts of all retrieved records. The second stage involved screening full-text articles of those studies that we judged to be potentially eligible from the first stage. We resolved any disagreements regarding study inclusion through discussion with a third review author (also from NDM, SS, OD and JLB). Screening was done using the Covidence software. We recorded the selection process in sufficient detail to complete a PRISMA flow diagram (Moher 2009), and a 'Characteristics of excluded studies' table.

Data extraction and management

For each included study, two review authors (from NDM, SS, OD, JLB and CZ) independently extracted data using a standardised electronic data collection form. We then entered data into Review Manager computer software for preparing Cochrane systematic reviews (RevMan 2024).

For each study, we extracted the following information, where available, and reported it in the Characteristics of included studies table.

- Methods: study name (if applicable), year of publication, country, study design, number of study centres, study setting, study recruitment procedure, and the definition of smoker used
- Participants: number, specific demographic characteristics (e.g. mean age, age range, gender, ethnicity, sexual orientation), mean cigarettes per day, and nicotine dependence (e.g. using Fagerström Test for Nicotine Dependence (FTND) scores (Heatherton 1991))
- Interventions: level (either individual-/group-level intervention delivered directly to PLWH who smoke, or system-change intervention), description of the intervention(s) (treatment, dosage, regimen, duration, intensity, content, format of delivery), and description of control (treatment, dosage, regimen, duration, intensity, content, format of delivery)
- Outcomes: cessation time points, the definition of cessation (e.g. continuous, prolonged or point prevalence abstinence), and biochemical validation. Other outcomes reported (e.g. HIV viral load, CD4 count, the incidence of opportunistic infections, AEs, SAEs)
- Notes: source of funding for the study and the study authors' declarations of interests

We also extracted all inclusion criteria and exclusion criteria, although we presented only the definition of smoker used in the Characteristics of included studies table.

We contacted authors of the studies by email where data were not available or unclear. For studies that were reported in more than one publication, we extracted the data from all publications onto separate data collection forms and then combined them. We resolved any disagreements in the data extracted by discussion with a third review author (from NDM, SS, OD and JLB).

Assessment of risk of bias in included studies

Randomised controlled trials

As recommended in chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions*, we utilised the risk of bias tool within RevMan 2024 to assess the risk of bias for RCTs (Higgins 2011; RevMan 2024). Two review authors (from NDM, SS, OD and JLB) independently assessed and reported the following information in the risk of bias table.

- Method of random sequence generation
- Method of allocation concealment
- Blind of participants or providers (as per guidance from the Cochrane Tobacco Addiction Group, we only assessed this domain in studies testing pharmacological interventions, as behavioural interventions cannot be blinded (Hartmann-Boyce 2023))
- Blind of outcome assessors
- Incomplete outcome data: numbers lost to follow-up or with an unknown outcome, for each outcome used in the review, by the intervention and control group
- Selective outcome reporting
- Any other threats to study quality. This included any other bias that was not associated with one of the other domains. For example, for cluster-RCTs, this included bias due to the recruitment of participants to clusters after allocation; baseline characteristics imbalanced; and no adjustments for the design effect during data analysis.

We judged each criterion to be at low, high or unclear risk of bias (Higgins 2011). We constructed a risk of bias table, which included justification for our risk of bias judgements. For each included study, we provided a summary assessment of the risk of bias where: 'low risk' was when there was low risk of bias across all domains; 'unclear risk', was when there was unclear risk of bias in one or more of the domains, but none was judged as high risk of bias; and 'high risk', when there was high risk of bias in one or more of the domains.

Non-randomised studies

Two review authors (NDM and OD) independently assessed and reported the risk of bias in non-randomised studies using the ROBINS-I tool across the following domains (Sterne 2016).

- Bias due to confounding
- Bias in selection of participants into the study
- Bias in classification of interventions
- Bias due to deviations from intended interventions
- Bias due to missing data
- Bias in measurement of outcomes
- Bias in selection of the reported result

We judged each criterion as low, moderate, serious, critical or unclear risk of bias (Sterne 2016). We provided a summary assessment of the risk of bias for each study where: 'low risk' was when there was low risk of bias across all domains; 'moderate risk' was when there was low or moderate risk of bias for all domains; 'serious risk' was when there was serious risk of bias in at least one domain, but not at critical risk of bias in any domain; 'critical risk' when there was critical risk of bias in at least one domain; and 'unclear risk' when there was no clear indication that the study was at serious or critical risk of bias and there was a lack of information in one or more key domains of bias.

We resolved any disagreements in the risk of bias assessments by discussion and consensus, or by consulting a third review author (also from NDM, SS, OD and JLB).

Measures of treatment effect

We calculated a risk ratio (RR) for tobacco use cessation for each study included in the meta-analysis as follows: (number of participants abstinent from tobacco in the intervention group/ number of participants in the intervention group)/(number of participants abstinent from tobacco in the control group/number of participants in the control group).

For the secondary outcomes, we used RR for dichotomous outcomes. Data for continuous outcomes were insufficient for meta-analysis, so where these were reported, we used the same measure of treatment effect reported in the original study. We did not identify any other types of outcomes.

We presented effect estimates with 95% confidence intervals (CI).

Unit of analysis issues

The unit of analysis for individual-/group-level interventions delivered directly to PLWH who use tobacco was the individual level. For organisational-level interventions, the unit of analysis could be the individual level (e.g. tobacco use cessation outcomes) or organisational level (e.g. the number of health professionals trained). Unit of analysis errors occur in studies where the unit of randomisation is a cluster (e.g. a healthcare facility), but the unit of analysis is individual participants without accounting for the clustering of individuals in the data (Rooney 1996). Where the unit of randomisation is a cluster, but the study did not include adjustments for clustering, we reduced the size of the study to the effective sample size using the original sample size from the study, divided by a design effect figure (Higgins 2022).

Studies with three or more arms

For studies that compared more than one intervention group to the control, and the intervention groups were not similar enough to warrant combining them to create a single group, we divided the control group into equal groups with the number of resulting groups being equal to the number of intervention groups. We then paired each of the resulting control groups with an intervention group and made independent comparisons. For example, for a three-arm study, we divided the control groups into two equal groups and made independent comparisons as follows: intervention one versus half of the control and intervention two versus half of the control. Splitting the control group in this way avoids double counting of participants in the results (Higgins 2022).

Dealing with missing data

Where we identified missing data, we contacted the study authors to request missing data. We also contacted study authors if aspects of study design or conduct were unclear. We noted the proportion of participants for whom data were missing in the risk of bias table.

For the primary outcomes, we used an intention-to-treat analysis approach and assumed that people lost to follow-up continued to use tobacco (West 2005).

Assessment of heterogeneity

We explored heterogeneity in clinical and methodological terms through consideration of the study populations, methods and interventions, and by visualisation of results, and in statistical terms, using the I^2 statistic (Higgins 2003). Where heterogeneity was more than 75%, we carried out further investigations (e.g. through subgroup analyses) if the data allowed (Deeks 2022).

Assessment of reporting biases

Searching multiple sources (as detailed in the search strategies above) should reduce reporting biases. We avoided language bias by not limiting the search terms by language, and used translation services where required. We did not exclude on the basis of publication status and aimed to minimise publication bias by the inclusion of grey literature, conference abstracts, and the inclusion of data from unpublished trials identified from trials registries (Li 2022). However, this was dependent on the data being obtained.

We assessed for selective reporting by comparing protocols and methods sections with published results.

We were unable to investigate possible publication bias using funnel plots because we identified fewer than 10 studies for each of the analyses.

Data synthesis

We extracted data from individual studies and reported them in table form. We then grouped studies according to the intervention(s) being evaluated and completed a meta-analysis of study results from RCTs within these groupings. We calculated quit rates based on numbers randomised to an intervention or control group. Where possible, we conducted intention-to-treat analyses, that is, including all participants initially assigned to intervention or control in their original groups. We excluded any deaths from the denominators. We treated any other losses to follow-up as continuing tobacco users, as described above. We also computed the other outcomes (i.e. quit attempts, receipt of a tobacco use cessation intervention, quality of life, HIV viral load, CD4 count, incidence of opportunistic infections and adverse events) based on numbers randomised to an intervention or control group and used intention-to-treat where possible. Where this was not possible, we clearly indicated how the analysis was carried out. We also clearly indicated where we simply reported the results as they were reported in the paper due to inadequate information to allow our intended analysis.

For meta-analysis with dichotomous outcomes, we pooled individual study risk ratios and 95% CIs using a Mantel-Haenszel random-effects model ((number of events in intervention condition/intervention denominator)/(number of events in control condition/control denominator)). Where the event is defined as tobacco use cessation, a risk ratio greater than one indicates that more people successfully quit in the treatment group than in the control group. We did not generate pooled estimates for any of the continuous outcomes as the data were insufficient for meta-analysis.

We did not include non-randomised studies in the meta-analyses, but summarised them narratively, prioritising adjusted over unadjusted effect estimates where possible (Reeves 2022). This was because of potential high levels of heterogeneity due to methodological diversity, as well as different sources and levels of risk of bias.

Subgroup analysis and investigation of heterogeneity

We were not able to conduct any preplanned subgroup analyses as there were not enough studies in the meta-analyses.

Sensitivity analysis

We did not perform any sensitivity analysis due to the small number of studies.

Summary of findings and assessment of the certainty of the evidence

Using GRADEpro software (GRADEproGDT 2015), we created summary of findings tables summarising evidence from RCTs for:

- long-term cessation (six months or longer) and serious adverse events for pharmacological interventions compared with placebo or another pharmacotherapy; and
- behavioural or system-change interventions compared with minimal or no intervention.

Two review authors (JLB; NM) worked together to assess the certainty of evidence using the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) (Schünemann 2022). We used methods and recommendations described in chapter 14 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2022). We justified all decisions to downgrade the certainty of the evidence using footnotes.

RESULTS

Description of studies

See Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies; and Characteristics of studies awaiting classification.

Results of the search

Figure 1 contains a flow diagram detailing the search results. Six out of 14 studies from the previous review (Pool 2016), were eligible for this current review. Eight were not eligible because of follow-up periods of less than six months. Our new searches identified 5461 potentially relevant records, including some studies from more than one record. We did not retrieve any records from searching other sources. After removing duplicates, 3986 records remained and were screened. After screening, we assessed 153 studies for eligibility, of which 25 were classified as ongoing and summarised in the Characteristics of ongoing studies, 116 were excluded (see Excluded studies), and one is awaiting classification (see Characteristics of studies awaiting classification). The remaining 11 were eligible for inclusion in the review, making a total of 17 eligible studies after combining with the six that were from the previous review. All 17 studies are included in the qualitative synthesis, with 9 of these also contributing to quantitative synthesis.

Figure 1. PRISMA flow diagram for 2023 update

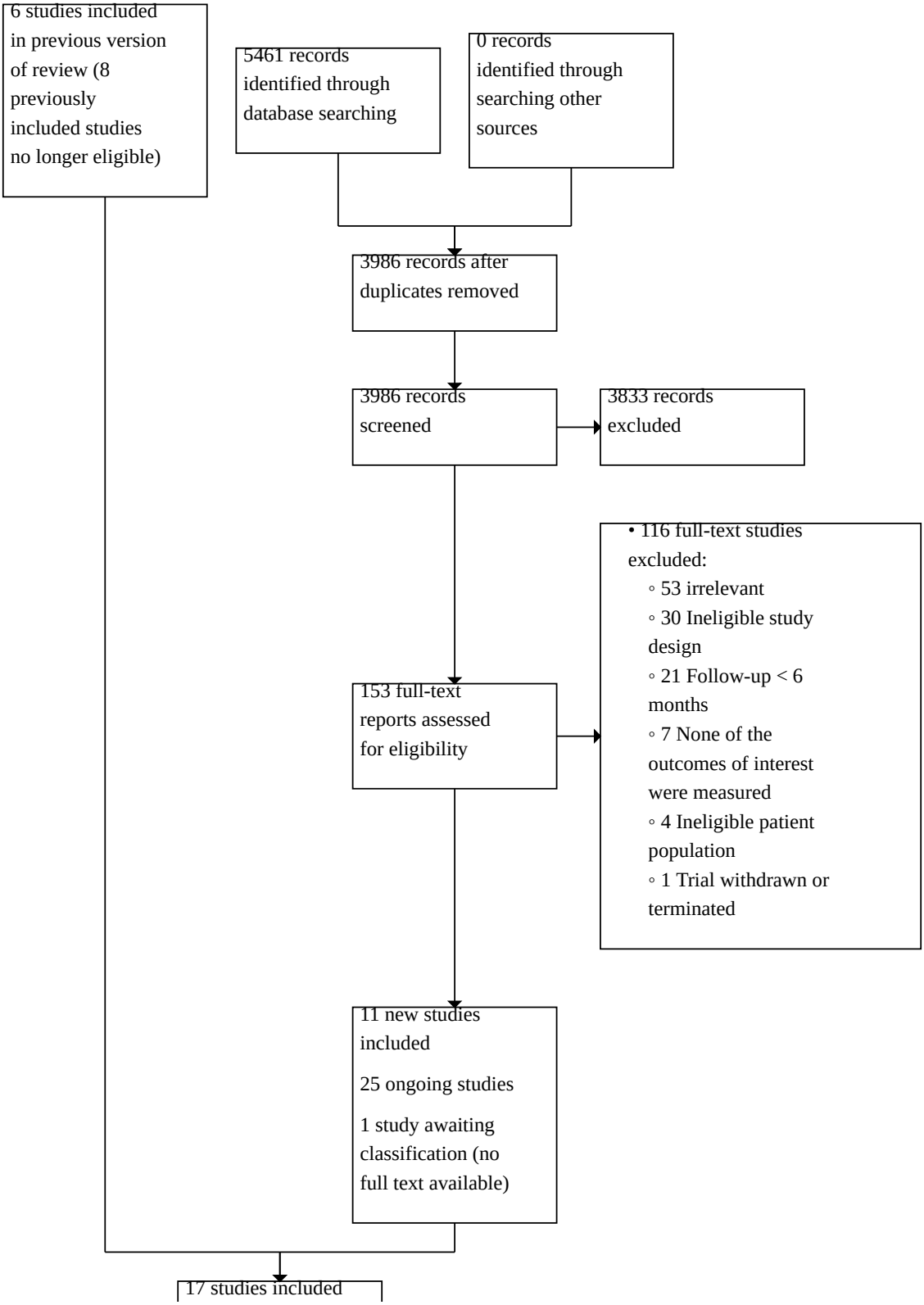
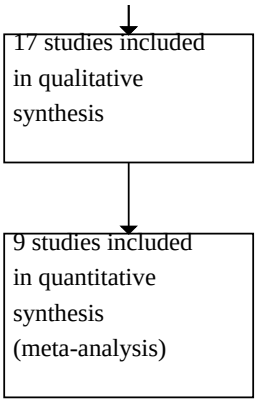


Figure 1. (Continued)



Included studies

The 17 included studies contributed a total of 9959 participants to the review, with sample sizes ranging from 15 (Wewers 2000), to 5808 (Huber 2012). All were conducted after 2000. Twelve of the 17 studies were from the USA, two from Switzerland (Gryaznov 2020; Huber 2012), and there was one study each from France (Mercie 2018), Russia (Tindle 2022) and South Africa (NCT01484340). Fifteen studies (4126 participants) were RCTs evaluating individual-/group-level interventions delivered directly to PLWH who use tobacco (Ashare 2019; Gryaznov 2020; Humfleet 2013; Kim 2018; Lloyd-Richardson 2009; Mercie 2018; NCT01484340; O'Cleirigh 2018; Shelley 2015; Shuter 2022; Stanton 2015; Stanton 2020; Tindle 2022; Vidrine 2012; Wewers 2000). The remaining two studies (5833 participants) evaluated system-change interventions: one of these was an RCT (Mussulman 2018), whilst the other was a natural experiment that compared the intervention site to the rest of the sites (Huber 2012).

Eight of the 17 included studies did not contribute to the quantitative synthesis because the interventions being evaluated or the comparisons made were unique and could not be grouped together with any other study (Huber 2012; Kim 2018; Mussulman 2018; NCT01484340; O'Cleirigh 2018; Stanton 2015; Tindle 2022; Wewers 2000). Results from these studies are described narratively. The nine studies (2741 participants) that contributed to quantitative synthesis were all individual-/group-level intervention studies where the interventions were delivered directly to PLWH who use tobacco either one-on-one (Ashare 2019; Gryaznov 2020; Humfleet 2013; Lloyd-Richardson 2009; Mercie 2018; Shelley 2015; Shuter 2022; Vidrine 2012), or in groups (Stanton 2020). Two of these nine were three-arm studies (Humfleet 2013; Shelley 2015).

One included study, NCT01484340, appeared complete, but the results were not available. We therefore used the study results emailed by one of the authors, Elf, on 28 June 2022 to Lindson, the lead author for another systematic review to which JLB is a co-author (Lindson 2023). The studies are described in detail in the Characteristics of included studies.

Participant characteristics

All participants were tobacco smokers. They were recruited through either one or a combination of the following: advertisements, postcards, flyers, letters sent to participants, from HIV clinics or well-established HIV cohorts, physician- or self-referral. All studies were in adults, with average ages ranging from 37 to 51 years. For 16 of the 17 studies, the majority of participants were male, with proportions ranging from 53% to 100%. The remaining study had 100% female participants (Kim 2018). Five studies did not report on race or ethnicity (Gryaznov 2020; Huber 2012; Mercie 2018; Tindle 2022; Wewers 2000). For the remaining studies, the majority of participants were black, reported in eight studies, with proportions ranging from 48% to 99.5% (Ashare 2019; Kim 2018; Mussulman 2018; NCT01484340; Shelley 2015; Shuter 2022; Stanton 2020; Vidrine 2012); white in two studies, with proportions of 53% and 52% (Humfleet 2013; Lloyd-Richardson 2009); Hispanic/Latino (100%) in one study for which having a Latino/Hispanic ethnicity was an inclusion criterion (Stanton 2015); and described as non-Hispanic in one study (87%; O'Cleirigh 2018). Eleven studies did not report on the sexual orientation of the participants. Where this was reported, the proportion of participants who were homosexual or bisexual varied from at least 25% to about 69% (Gryaznov 2020; Huber 2012; Humfleet 2013; Mercie 2018; Stanton 2020; Vidrine 2012).

Fifteen studies reported the average number of cigarettes per day and this ranged from 10 to 27.5 (Ashare 2019; Gryaznov 2020; Humfleet 2013; Kim 2018; Lloyd-Richardson 2009; Mercie 2018; Mussulman 2018; NCT01484340; O'Cleirigh 2018; Shelley 2015; Shuter 2022; Stanton 2020; Tindle 2022; Vidrine 2012; Wewers 2000). Eleven studies reported on nicotine dependence, and eight of these used mean FTND scores, which ranged from 4.9 to 5.9, indicating moderate dependence on average (Humfleet 2013; Kim 2018; Lloyd-Richardson 2009; Mercie 2018; O'Cleirigh 2018; Stanton 2020; Vidrine 2012; Wewers 2000). One study reported a proportion with high dependence of 9.5% using the FTND (Shuter 2022). Two studies used the Heaviness of Smoking Index, and reported proportions with high dependence of 67% and 40% respectively (Ashare 2019; Mussulman 2018). For 11 studies, the inclusion criteria explicitly required participants to be willing to quit in the near future (e.g. within the next two to four weeks, or six months in some cases), or be motivated to quit (Kim

2018; Mercie 2018; Mussulman 2018; NCT01484340; O'Cleirigh 2018; Shelley 2015; Shuter 2022; Stanton 2020; Tindle 2022; Vidrine 2012; Wewers 2000). This was not mentioned in the remaining six studies (Ashare 2019; Gryaznov 2020; Huber 2012; Humfleet 2013; Lloyd-Richardson 2009; Stanton 2015).

Six studies excluded those with psychiatric disorders such as a history of psychosis or a suicide attempt, depression, bipolar disorder, and anxiety (Ashare 2019; Kim 2018; Mercie 2018; Shelley 2015; Vidrine 2012), or unstable psychiatric illness (Tindle 2022), with four of these also excluding those with either hazardous alcohol use or an alcohol use disorder (Ashare 2019; Kim 2018; Mercie 2018; Shelley 2015). Those who had substantial problems with the use of, or were dependent on, psychoactive substances other than tobacco were excluded from three studies (Kim 2018; Mercie 2018; Shelley 2015). These exclusions were more likely for studies where varenicline was used.

From four studies that reported income, 70% to 90% of participants were from low-income backgrounds in three studies (Ashare 2019; Humfleet 2013; Shuter 2022), and for the remaining study, 25% could not make ends meet financially (Stanton 2020). Where unemployment rates were reported, it was 25% to 81% for five studies (Humfleet 2013; Lloyd-Richardson 2009; Stanton 2020; Vidrine 2012; Wewers 2000), whilst in one study only 10% of participants were in full time employment (Stanton 2015). The proportion of participants with high school education or less varied from 27% to 88% for nine studies (Ashare 2019; Humfleet 2013; Kim 2018; Lloyd-Richardson 2009; Shelley 2015; Shuter 2022; Stanton 2015; Vidrine 2012; Wewers 2000), whilst two studies reported proportions with at least some college education of 35% (Stanton 2020), and 65% (O'Cleirigh 2018), and two reported that 77% and 97.5% had at least nine years of education, respectively (Gryaznov 2020; Tindle 2022). The remaining studies did not report on education.

Individual-/group-level intervention studies

Studies that investigated tobacco use cessation pharmacotherapies provided some degree of brief advice or behavioural support to both the intervention and control group. Those investigating behavioural-support interventions also provided, offered, or gave instructions to obtain pharmacotherapy. Although the review was interested in tobacco cessation generally, all included studies evaluating individual-/group-level interventions focused on cigarette smoking cessation. The interventions, as well as the controls, are described below.

Description of the intervention: behavioural

Provider

We categorised the provider of the behavioural interventions as follows: healthcare professionals, researchers, peers or co-facilitated by a peer and a professional. For 11 of the 15 individual-/group-level intervention studies, the intervention was provided by healthcare professionals who were described as counsellors (Ashare 2019; Shelley 2015; Vidrine 2012), physicians (Gryaznov 2020; Tindle 2022), social workers or psychologists (Humfleet 2013; O'Cleirigh 2018), tobacco treatment specialists including graduate students (Kim 2018), health educators (Lloyd-Richardson 2009; Stanton 2015), or simply as healthcare professionals (Mercie 2018). Study interventionists delivered the intervention in one study (NCT01484340), whilst for the remaining three, this was facilitated by peers who had diagnosed HIV and were current or former smokers (Shuter 2022), or co-facilitated by an ex-smoker with diagnosed HIV alongside a professional (Stanton 2020; Wewers 2000).

Where specific training on tobacco use cessation intervention delivery was mentioned, this was either tobacco treatment specialist training (Kim 2018; Lloyd-Richardson 2009; Stanton 2020; Wewers 2000), or specific training on the implementation of the study intervention (Ashare 2019; Kim 2018; Shelley 2015; Stanton 2015; Vidrine 2012). In one study, the people delivering the intervention were specifically described as having previous experience in smoking cessation treatment delivery (Humfleet 2013). For the remaining studies, while the academic qualifications of the people delivering the interventions were provided, little detail was provided about their tobacco use cessation treatment training or counselling experience.

Mode of contact

For 11 of the included individual-/group-level intervention studies, the behavioural intervention component was partly or wholly delivered face-to-face (Ashare 2019; Gryaznov 2020; Humfleet 2013; Lloyd-Richardson 2009; Mercie 2018; NCT01484340; O'Cleirigh 2018; Stanton 2015; Stanton 2020; Tindle 2022; Wewers 2000). Out of these 11, three also involved intervention delivery by telephone voice calls (Ashare 2019; Stanton 2015; Wewers 2000); whilst in the study by Humfleet 2013, one of the intervention groups also received part of the intervention as web-based, and in another study part of the behavioural support was received via a computer app (Gryaznov 2020).

Of the remaining four studies, the behavioural intervention components were delivered either as telephone voice or video calls, text messages or through the web alone or in combination (Kim 2018; Shelley 2015; Shuter 2022; Vidrine 2012). Kim 2018 specifically tested two different delivery modalities of the same intervention against each other, that is, telephone voice calls versus video calls. Additional resources were provided in most studies, such as written materials.

About 27% (n = 4/15) of the interventions offered more than eight face-to-face, telephone or web-based sessions (Mercie 2018; O'Cleirigh 2018; Vidrine 2012; Wewers 2000); whilst this was four to eight sessions for 53% (n = 8/15) of the studies (Ashare 2019; Kim 2018; Humfleet 2013; Lloyd-Richardson 2009; Shelley 2015; Shuter 2022; Stanton 2015; Stanton 2020), one session for 7% (n = 1/15) of the studies (Tindle 2022), and unclear for 13% (n = 2/15) (Gryaznov 2020; NCT01484340).

For 14 studies, the interventions were delivered to individuals, whilst this was to groups of individuals for one study (Stanton 2020). For studies where the planned total contact time for interventions delivered either face-to-face or via the telephone was clearly reported, this varied between 91 minutes and 720 minutes. This does not account for time spent using web-based or app-based interventions or reviewing text messages.

Tailoring

Eleven of the interventions were specifically tailored to PLWH. This was achieved through a range of methods, including educating the smokers about the unique risks of smoking among PLWH (Ashare 2019; Humfleet 2013; Kim 2018; Lloyd-Richardson 2009; O'Cleirigh

2018; Shelley 2015; Shuter 2022; Stanton 2015; Stanton 2020; Vidrine 2012), and facilitation by current- or ex-smoker peers with diagnosed HIV (Shuter 2022; Stanton 2020; Wewers 2000). Some interventions also addressed other problems that are common among PLWH who smoke, including comorbid psychiatric illness such as stress, anxiety and depression, social isolation or the use of other psychoactive substances, in addition to addressing smoking (Humfleet 2013; O'Cleirigh 2018; Stanton 2020; Tindle 2022). Some trial authors did not describe how the intervention was tailored in detail. In the text message group of Shelley 2015, the text messages did not contain the words HIV or AIDS in order to ensure confidentiality, although the messages were designed to emphasise particular barriers faced by PLWH, such as stress. We did consider this intervention tailored, but recognise that the degree of tailoring varies between studies.

Description of interventions: pharmacotherapy

Nine studies provided NRT as patches or gum or both (Humfleet 2013; Kim 2018; Lloyd-Richardson 2009; NCT01484340; O'Cleirigh 2018; Shuter 2022; Stanton 2015; Stanton 2020; Wewers 2000). In an additional two studies, NRT was offered at the physician's discretion (Gryaznov 2020), or the participants received instructions to obtain NRT patches (Vidrine 2012). Ashare 2019, Mercie 2018, Shelley 2015 and Tindle 2022 used varenicline instead. Tindle 2022 also used cytisine in one of the intervention arms. No studies included other smoking cessation pharmacotherapies, such as bupropion, in their protocol.

Description of controls

Where the intervention under investigation was pharmacotherapy, the control group received the same behavioural support as the intervention group (Ashare 2019; Mercie 2018; NCT01484340; Tindle 2022). In one study, the control group also received NRT as a spray (Tindle 2022). In three of these studies, the control group also received a placebo of the pharmacotherapy under investigation (Ashare 2019; Mercie 2018; Tindle 2022).

In studies where the intervention under investigation was behavioural support, the control groups received: brief advice (Gryaznov 2020); enhanced standard smoking cessation therapy (O'Cleirigh 2018); attention-matched behavioural support (Shuter 2022); or the same pharmacotherapy as the intervention group alone (Shelley 2015), or with brief advice (Humfleet 2013; Lloyd-Richardson 2009; Stanton 2020), or behavioural support of different intensity (Stanton 2015). For Vidrine 2012, the control group also received instructions on how to obtain NRT patches in addition to brief advice. For Wewers 2000, the control group was written materials and a letter with a strong quit smoking message.

Outcomes

The longest follow-up period in individual-/group-level intervention studies varied, with many (n = 7) studies having follow-up of six months (Ashare 2019; Gryaznov 2020; Kim 2018; Lloyd-Richardson 2009; O'Cleirigh 2018; Shelley 2015; Shuter 2022); for the remaining studies follow-up was 7.5 months (Stanton 2020), eight months (Wewers 2000), and 12 months (Humfleet 2013; Mercie 2018; NCT01484340; Stanton 2015; Tindle 2022; Vidrine 2012).

Cessation outcomes were measured as continuous abstinence in four studies (Ashare 2019; Gryaznov 2020; Kim 2018; Mercie 2018), and as seven-day point prevalence abstinence in 10 studies (Humfleet 2013; Lloyd-Richardson 2009; O'Cleirigh 2018; Shelley 2015; Shuter 2022; Stanton 2015; Stanton 2020; Tindle 2022; Vidrine 2012; Wewers 2000); but was unclear for the remaining study (NCT01484340). Self-reported cessation outcomes were biochemically verified in all 15 studies, either using exhaled carbon monoxide (eCO) (Ashare 2019; Gryaznov 2020; Humfleet 2013; Lloyd-Richardson 2009; Mercie 2018; O'Cleirigh 2018; Shelley 2015; Shuter 2022; Stanton 2015; Stanton 2020; Tindle 2022; Vidrine 2012; Wewers 2000), cotinine concentrations (Kim 2018), or a combination of both (NCT01484340). For eCO concentrations, cut-off points varied from 4 parts per million (ppm) or less (O'Cleirigh 2018), 7 ppm or less (Gryaznov 2020; NCT01484340; Vidrine 2012), 8 ppm or less (Ashare 2019; Shelley 2015; Wewers 2000), through to 10 ppm or less (Humfleet 2013; Lloyd-Richardson 2009; Mercie 2018; Shuter 2022; Stanton 2015; Stanton 2020; Tindle 2022). For cotinine, this was either less than 0.4 µg/mL (NCT01484340) or 10 ng/mL or higher (Kim 2018).

The only studies to report on adverse events were those that evaluated pharmacotherapy (Ashare 2019; Mercie 2018; NCT01484340). Two studies reported quit attempts (Shuter 2022; Stanton 2015), one reported HIV-1 viral load and CD4 count (Mercie 2018), and one reported all-cause mortality (NCT01484340). None of the studies reported on incidence of opportunistic infections or quality of life outcomes.

System-change intervention studies

The two studies that evaluated system-change interventions focused on cigarette smoking cessation. One evaluated an intervention comprising physician training plus a physicians' checklist for semi-annual documentation of counselling versus usual care (Huber 2012). The other study, Mussulman 2018, compared the effects of a 'warm handoff' referral system to fax referral. Both studies also provided either pharmacotherapy or pharmacotherapy information. The interventions, as well as the controls, are described below.

Description of the intervention: behavioural

Huber 2012 directed the intervention at physicians at the HIV outpatient clinic at the University Hospital Zurich. They received standardised, half-day training on smoking cessation delivered by trainers of the Swiss Lung Association. The training included information on identification of smokers, nicotine dependence, nicotine withdrawal-related problems, motivation stages of intended behavioural change of substance-dependent people, methods of counselling, and pharmacological support of smoking cessation. At every cohort visit during the intervention period, physicians had to complete a short checklist to document the participants' smoking status, their current motivation level to stop smoking, and the physician's support offered at this visit. Support for smoking cessation included short or detailed counselling about problems associated with smoking cessation, information on medication (nicotine, bupropion and varenicline), arranging a follow-up appointment for further discussion about smoking cessation, and, if appropriate, planning a date for smoking cessation.

Mussulman 2018 evaluated a 'warm handoff', where an initial brief intervention comprising assessing withdrawal, adjusting nicotine replacement to ensure patient comfort, and describing warm handoff procedures, was delivered. Staff then performed the warm

handoff by calling the quitline, notifying the quitline that an inpatient was on the line, transferring the call to the patient's mobile or bedside hospital phone for enrolment and an initial counselling session, and then leaving the room. After the quitline session, the counsellor checked back with the patient to follow up on decisions made during the counselling session, such as arranging for medication scripts on discharge. Participants also received a standard cessation brochure with information and resources for quitting smoking and quitline information.

Description of interventions: pharmacotherapy

It is not clear whether the participants in Huber 2012 were provided with pharmacotherapy, but they were given information on NRT, bupropion and varenicline. Participants in the study by Mussulman 2018 were provided with NRT.

Description of controls

The control condition in Huber 2012 was standard care, although this was not clearly described. Smokers were given frequent short counselling, and half of the institutions also reported offering 'detailed counselling' if indicated, and around half reported handing out information booklets. Also, institutions reported using nicotine substitution, or prescribing bupropion or varenicline to some participants. All institutions reported referring participants to specialised addiction treatment institutions if they so wished.

Staff in Mussulman 2018 sent a fax to the quitline referring the control group participants to the service on the day they were discharged from the hospital. The control participants also received the standard hospital screening and intervention procedures: assessing withdrawal; adjusting inpatient nicotine replacement to enhance patient comfort; and providing assistance in quitting, which included developing a quit plan and arranging medication prescriptions on discharge. They also received the same standard cessation brochure with information and resources for quitting smoking and quitline information as in the warm handoff group.

Outcomes

The longest follow-up period for Huber 2012 was three years, and self-reported continuous abstinence was not biochemically verified. For Mussulman 2018, the longest follow-up period was six months, and self-reported seven-day point prevalence abstinence was verified using saliva cotinine (cut off ≤ 15 ng/mL). Other relevant outcomes included receipt of cessation pharmacotherapy, use of cessation pharmacotherapy after discharge from hospital, enrolment in the quitline, and recorded smoking cessation counselling.

Funding sources

All studies received funding from independent national- or institutional-level funding. Three of the studies received study medication free of charge from a pharmaceutical company, Pfizer (Ashare 2019; Mercie 2018; Shelley 2015).

Excluded studies

Of the 116 studies we excluded, 53 were irrelevant, leaving 63 that were most potentially relevant. These 63 are listed in the Characteristics of excluded studies along with reasons for exclusion. The most common reasons for exclusion were ineligible study design (30 studies), or a follow-up period of less than six months (21 studies). We excluded seven of the 63 studies because they did not measure any of the outcomes of interest, four were ineligible on the basis of the study population, and one was a withdrawn study.

Ongoing studies

Of the 25 ongoing studies, 19 were in the USA (Cioe 2021; Edelman 2021; Garey 2021; Marhefka 2021; McClure 2021; McKetchnie 2021; NCT01886924; NCT01965405; NCT02460900; NCT02982772; NCT03670316; NCT04176172; NCT04725617; NCT04808609; NCT04994444; NCT05019495; NCT05030766; NCT05339659; Vidrine 2021), two in Canada (Côté 2015; NCT01800019), with one each for Botswana (NCT04532970), China (NCT05020899), Kenya (NCT03342027) and Vietnam (NCT05162911) (see Characteristics of ongoing studies).

There were two, three-group, parallel-design RCTs, and three 2x2 factorial RCTs, with the rest being two-group parallel-design RCTs. Of the 22 two- and three-group RCTs, 15 are evaluating behavioural-support interventions against standard care or other active comparators (Cioe 2021; Côté 2015; Garey 2021; Marhefka 2021; McClure 2021; McKetchnie 2021; NCT01886924; NCT04176172; NCT04532970; NCT04725617; NCT04808609; NCT05019495; NCT05020899; NCT05339659; Vidrine 2021), three are evaluating contingency management interventions (Edelman 2021; NCT01965405; NCT05030766), whilst NCT02982772 is evaluating an NRT dosage algorithm, NCT03670316 sequential treatment with varenicline, bupropion or NRT with the order determined using an algorithm, NCT04994444 one evaluated NRT preloading, and NCT05162911 is comparing referral to a quitline versus onsite counselling with or without NRT. The three 2x2 factorial RCTs are evaluating pharmacotherapy (NRT, varenicline or bupropion) and behavioural support (NCT01800019; NCT02460900; NCT03342027). Of the 25 ongoing studies, we classified 24 as individual-/group-level intervention studies, whilst one was a system-change intervention study (NCT05162911).

Risk of bias in included studies

The results of the risk of bias assessments are summarised below; the results of the assessment for the 16 RCTs are presented separately to those of the one non-randomised study.

Of the 16 RCTs, three were at low risk of bias overall, five were at high risk of bias, and eight were at unclear risk. Figure 2 presents a summary of the review authors' judgements about each risk of bias item as percentages across all included RCTs. Figure 3 shows a summary of the risk of bias profile for each RCT across all domains evaluated. We judged the non-randomised study, Huber 2012, at serious risk of bias overall.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

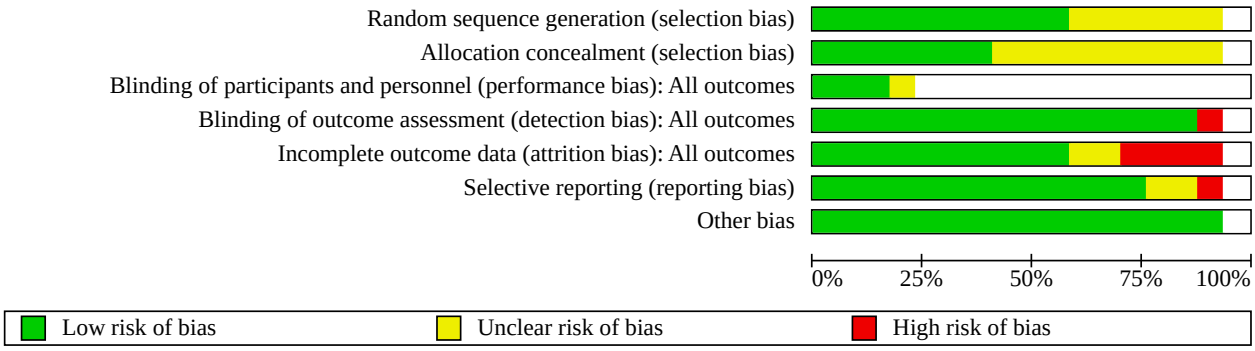


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

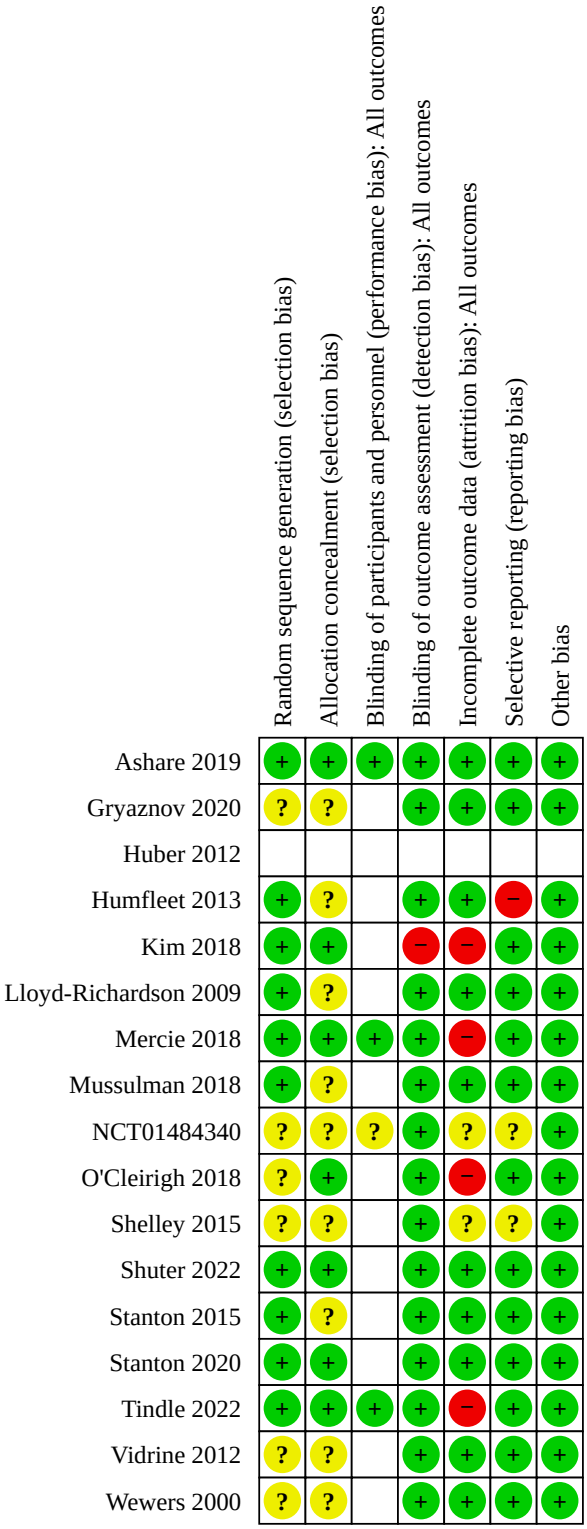


Figure 3. (Continued)

Allocation

Ten of the 16 RCTs clearly described random sequence generation using computer-based randomisation procedures (Ashare 2019; Humfleet 2013; Kim 2018; Lloyd-Richardson 2009; Mercie 2018; Mussulman 2018; Shuter 2022; Stanton 2015; Tindle 2022; Stanton 2020). We judged six studies as unclear due to insufficient information to reach a judgement.

Seven RCTs clearly described allocation concealment, and this included the use of central randomisation by staff not involved in participant recruitment or enrolment (Ashare 2019; Mercie 2018; Shuter 2022; Stanton 2020; Tindle 2022), the use of sealed envelopes (Kim 2018), and password protection (O'Cleirigh 2018). We judged the remaining nine RCTs as unclear for allocation concealment due to insufficient information to reach a judgement.

Blinding

Of the four RCTs that evaluated pharmacotherapy, three achieved the blinding of study participants and study personnel through the use of a placebo (Ashare 2019; Mercie 2018; Tindle 2022); whilst the remaining study did not use a placebo and did not describe blinding of participants and study personnel (NCT01484340). We judged blinding of participants and study personnel as not applicable for the remaining 12 RCTs because of the nature of the interventions.

Four of the 16 RCTs specified blinding of outcome assessment (Lloyd-Richardson 2009; Mussulman 2018; O'Cleirigh 2018; Shuter 2022). We judged all but one of the remaining RCTs as low risk of detection bias because the cessation outcomes were biochemically verified. We judged Kim 2018 as high risk of detection bias because there was no blinding of outcome assessors, and biochemical verification of cessation outcomes was done by the participants at home.

Incomplete outcome data

We judged four out of the 16 RCTs to be at high risk of attrition bias because of a higher proportion of loss to follow-up in one group than the other (Kim 2018; O'Cleirigh 2018; Tindle 2022), or over 50% loss to follow-up in both arms (Mercie 2018). For Wewers 2000, the distribution of missing participants was unbalanced between groups, with high loss to follow-up in the control group at eight months. However, since no control participants reported abstinence at eight weeks, this would not have affected the outcome, so we judged it as low risk. Attrition bias was unclear for two RCTs due to inadequate reporting (NCT01484340; Shelley 2015). We judged the remaining nine studies as low risk of attrition bias due to low attrition (Gryaznov 2020), no differences in attrition between groups (Ashare 2019; Humfleet 2013; Lloyd-Richardson 2009; Shuter 2022; Stanton 2015; Stanton 2020; Vidrine 2012), or the use of intention-to-treat with those lost to follow-up considered as smokers, or both (Lloyd-Richardson 2009; Mussulman 2018; Shuter 2022; Stanton 2015; Stanton 2020; Vidrine 2012).

Selective reporting

We judged one of the 16 RCTs to be at high risk of reporting bias because outcome measures were not reported as described in the protocol (Humfleet 2013). The authors stated in the protocol that sustained abstinence and point prevalence abstinence outcomes would be assessed; however, they only reported point prevalence abstinence outcomes without explanation. We obtained sustained abstinence data via communication with the trial authors; however, we used point prevalence abstinence outcomes in the meta-analysis, since the authors' definition of sustained abstinence (defining relapse as seven consecutive days of smoking) means that point prevalence abstinence is the strictest definition of abstinence. For two RCTs, there was not enough information to make judgements on the risk of reporting bias (NCT01484340; Shelley 2015). We judged the risk of reporting bias as low for the remaining 13 studies.

Other potential sources of bias

We did not judge any of the RCTs to be at risk of other bias.

Risk of bias in non-randomised studies

We judged risk of bias due to confounding in Huber 2012 as serious because some important confounders, such as alcohol consumption, were only measured in a subset of participants and therefore were not included in the main analysis (Table 1). We judged the risk of bias in the selection of participants into the study as low because all eligible patients at participating sites with relevant information were included in the analysis. There were also no concerns about bias in classification of interventions, due to deviations from intended interventions, due to missing data (follow-up rate was high), or in selection of the reported results, so we judged the risk of bias for these domains as low. However, we judged the risk of bias in measurement of tobacco use cessation outcomes as serious because it was from self-reports without biochemical validation. Overall, therefore, we judged Huber 2012 to be at serious risk of bias.

Effects of interventions

See: **Summary of findings 1** Behavioural support or system change interventions compared with no or less intensive behavioural support for tobacco use cessation in people living with HIV; **Summary of findings 2** Pharmacological interventions compared with placebo, no intervention, or another pharmacotherapy for tobacco use cessation in people living with HIV

Individual-/group-level interventions delivered directly to PLWH who use tobacco

We report the results according to the interventions under evaluation or comparisons made, that is, behavioural support versus brief advice or no intervention; behavioural support plus NRT versus brief advice; behavioural support versus a different type of behavioural support; behavioural support plus NRT versus behavioural support alone; varenicline versus placebo; varenicline

versus NRT; cytisine versus NRT and studies testing intervention delivery modalities.

Behavioural support versus brief advice or no intervention

Seven studies contributed to this analysis with a total of 2314 participants. Of these, two compared behavioural support alone versus brief advice alone (555 participants; Gryaznov 2020; Vidrine 2012), four compared behavioural support plus NRT versus brief advice plus NRT (1601 participants; Humfleet 2013; Lloyd-Richardson 2009; Shuter 2022; Stanton 2020), and one compared behavioural support plus varenicline versus varenicline alone (158 participants; Shelley 2015).

Tobacco use cessation outcomes

A pooled estimate combining the seven included studies did not show clear evidence of a difference in smoking abstinence rates between intervention and control arms (risk ratio (RR) 1.11, 95% confidence interval (CI) 0.87 to 1.42; low-certainty evidence; Analysis 1.1; Summary of findings 1), with no evidence of heterogeneity (I^2 = 0%). Abstinence in the control group was 10% (108/1121) and in the intervention group it was 11% (127/1193).

There was no evidence of benefit from behavioural support alone when compared to brief advice alone (RR 0.84, 95% CI 0.44 to 1.59), with no evidence of heterogeneity (I^2 = 0%; Gryaznov 2020; Vidrine 2012). This was from two studies with 555 participants in total; abstinence in the control group was 7% (19/277) and in the intervention group it was 6% (16/278).

There was also no clear evidence of a benefit from the four studies that compared behavioural support plus NRT to brief advice plus NRT (RR 1.17, 95% CI 0.90 to 1.53), with no evidence of heterogeneity (I^2 = 0%; Humfleet 2013; Lloyd-Richardson 2009; Shuter 2022; Stanton 2020). The total number of participants included in this comparison was 1601; abstinence in the control group was 11% (87/791) and in the intervention group it was 13% (108/810). Nevertheless, one of these four studies suggested a benefit from real-time social support through an online social network when compared to an attention-matched control (RR 1.70, 95% CI 1.04 to 2.79; Shuter 2022).

The three-arm study by Shelley 2015, compared adherence-focused text messages plus varenicline, adherence-focused text messages and cell phone-delivered counselling plus varenicline, and varenicline only. When considering the two behavioural-support-plus-varenicline groups together compared to varenicline alone, there was no evidence of benefit (RR 0.75, 95% CI 0.13 to 4.44). Abstinence in the varenicline group was 4% (2/53) and in the behavioural support plus varenicline group it was 3% (3/105). When considering the intervention group that received adherence-focused text messages plus varenicline versus the control (i.e. varenicline alone), the RR was 0.53 (95% CI 0.03 to 8.14), with an abstinence in the varenicline group of 4% (1/27) and in the adherence-focused text messages plus varenicline group of 2% (1/51). When considering the other comparison between the intervention group that received adherence-focused text messages and cell phone-delivered counselling plus varenicline versus the control (i.e. varenicline alone), the RR was 0.96 (95% CI 0.09 to 10.14), with an abstinence in the varenicline group of 4% (1/26) and in the adherence-focused text messages and cell phone-delivered counselling plus varenicline group of 4% (2/54).

All three comparisons are based on few studies and the confidence intervals include the potential for both benefit and no benefit.

Quit attempts

Only one study out of the seven in this group reported on intervention effects on quit attempts (Shuter 2022), so it was not possible to perform a quantitative synthesis. The multimodal platform, interactive web intervention, hosted within an online social network to support quitting among PLWH who smoke resulted in a significantly higher proportion (26%; 67/255) of participants reporting making a quit attempt on the selected quit day compared to the control condition (18%; 44/251; RR 1.50, 95% CI 1.07 to 2.10; Analysis 1.2). There were no differences between conditions in the mean number of days quit among participants who made a quit attempt.

No studies in this group measured the other outcomes, that is, AEs, SAEs, the proportion of patients who are tobacco users at the time of a consultation who receive a tobacco use cessation intervention, quality of life, HIV outcomes (viral load, CD4 count), and incidence of opportunistic infections. It was therefore not possible to perform the planned quantitative syntheses.

Behavioural support plus NRT versus brief advice

Only one small study (15 participants) in this group compared a behavioural-support intervention comprising three face-to-face individual counselling sessions, weekly phone calls over eight weeks with additional calls as required, written materials and NRT patches to a control comprising written materials and a letter with a strong quit smoking message (Wewers 2000).

Tobacco use cessation outcomes

While the point estimate favoured behavioural support plus NRT compared with brief advice alone, confidence intervals were extremely wide and included the potential for both benefit and no benefit from the intervention (RR 8.00, 95% CI 0.51 to 126.67; very low-certainty evidence; Analysis 2.1; Summary of findings 2). None of the seven participants in the control group achieved smoking abstinence, whilst this was 50% (4/8) in the intervention group.

The other relevant outcomes (i.e. quit attempts, AEs, SAEs, the proportion of patients who are tobacco users at the time of a consultation who receive a tobacco use cessation intervention, quality of life, HIV outcomes (viral load, CD4 count), and incidence of opportunistic infections) were not measured in this study.

Behavioural support versus a different type of behavioural support

The two studies in this category evaluated very different interventions.

- Stanton 2015 compared behavioural support comprising physician brief advice, four additional face-to-face individual counselling sessions (average duration of session 1: 62 minutes), three, 10-minute phone calls and written material to less intensive behavioural support comprising physician brief advice, plus two face-to-face individual counselling sessions and one quit day phone call (10 minutes), and written materials. Participants in both groups received NRT.
- O'Cleirigh 2018, on the other hand, compared a hybrid cognitive behavioural therapy targeting smoking cessation, anxiety and

depression simultaneously, which was delivered across nine, 60-minute sessions to an enhanced standard smoking intervention comprising four post-quit, 10-minute sessions. Participants in both groups also received a 60-minute psychoeducation session plus NRT.

A quantitative analysis of these two studies was not deemed possible. The results, therefore, are described narratively below.

Tobacco use cessation outcomes

In Stanton 2015 (302 participants), there was no evidence of a difference in smoking abstinence between more and less intensive behavioural support (RR 0.96, 95% CI 0.41 to 2.24; Analysis 3.1). Abstinence was achieved by 6% (10/154) of participants in the more intensive intervention group and 7% (10/148) in the less intensive intervention group.

For O'Cleirigh 2018 (53 participants), the hybrid cognitive behaviour therapy intervention targeting smoking cessation, anxiety and depression simultaneously was more effective for smoking cessation than the enhanced standard smoking intervention (RR 12.46, 95% CI 1.74 to 89.15; Analysis 3.1). Abstinence was achieved by 46% (12/26) of participants in the hybrid cognitive behaviour therapy intervention group and only 4% (1/27) in the enhanced standard smoking intervention group. Nevertheless, this is a very small study of 53 participants, where 36% (19/53) were lost to follow-up, although a higher percentage was lost to follow-up in the hybrid cognitive behaviour therapy intervention group (50%; 13/26) than in the enhanced standard smoking intervention group (22%; 6/27). The method of random sequence generation was also unclear for this study.

Quit attempts

Stanton 2015 also reported that the proportion of participants who made at least one quit attempt during the study was not different between groups: 34% (52/154) for the more intensive intervention, and 41% (60/148) in the less intensive intervention group (RR 0.83, 95% CI 0.62 to 1.12; Analysis 3.2).

No studies in this group measured the other outcomes (i.e. AEs, SAEs, the proportion of patients who are tobacco users at the time of a consultation who receive a tobacco use cessation intervention, quality of life, HIV outcomes (viral load, CD4 count) and incidence of opportunistic infections).

Behavioural support plus NRT versus behavioural support alone

The one study (560 participants) in this group evaluated behavioural support plus NRT versus behavioural support alone (NCT01484340). For both groups, behavioural support comprised self-help material plus advice to quit smoking following the 5A's model for smoking cessation counselling with five discrete components: (1) Ask about smoking at every opportunity; (2) Advise the patient to quit smoking; (3) Assess readiness to quit; (4) Assist the patient in quitting; and (5) Arrange follow-up. At the time of writing, the results paper had not been published; we obtained the study results reported here from communication with the study author, Elf, in an email to Lindson, the lead author of another systematic review to which JLB is a co-author (Lindson 2023), on 28 June 2022, and the trials registry.

Tobacco use cessation outcomes

While the point estimate favoured the addition of NRT to behavioural support, confidence intervals crossed 1, indicating the potential for no benefit (RR 1.47, 95% CI 0.92 to 2.36; low-certainty evidence; Analysis 4.1; Summary of findings 2). Abstinence was achieved by ~14% (38/279) of participants receiving behavioural support plus NRT, and 9% (26/281) in the behavioural-support-only group. From the trial registry, the smoking cessation outcomes were reported in terms of median eCO concentrations. This was similar between groups at the end of 12 months (median (interquartile range (IQR)) = 10 (5 to 17) ppm for the behavioural-support-only group and 10 (5 to17) ppm for behavioural-support plus NRT; NCT01484340).

Serious adverse events

The number of participants who experienced SAEs was also similar between groups (NCT01484340): 1.8% (5/279) for behavioural support plus NRT and 1.4% (4/281) for the behavioural-support-only group (RR 1.26, 95% CI 0.34 to 4.64; low-certainty evidence; Analysis 4.2; Summary of findings 2).

NCT01484340 also reported on all-cause mortality separately and this was similar between groups: 1.4% (4/279) for the group receiving behavioural support plus NRT, and 1.1% (3/281) for the behavioural-support-only group (RR 1.34, 95% CI 0.30 to 5.95; Analysis 4.3).

The other relevant outcomes (i.e. quit attempts, AEs, the proportion of patients who are tobacco users at the time of a consultation who receive a tobacco use cessation intervention, quality of life, HIV outcomes (viral load, CD4 count) and incidence of opportunistic infections) were not measured in this study.

Varenicline versus placebo

Two studies contributed to this analysis with a total of 427 participants (Ashare 2019; Mercie 2018). Both studies compared varenicline with placebo of identical appearance and dosing regimen. Varenicline was provided based on US Food and Drug Administration (FDA) labelling: Day 1 to Day 3: 0.5 mg once daily; Day 4 to Day 7: 0.5 mg twice daily; and Day 8 to Day 84: 1.0 mg twice daily. In one of the studies, participants in both groups also received behavioural support comprising six, standardised, one-on-one smoking cessation counselling sessions (Ashare 2019). In the other study, participants in both groups also received behavioural support comprising 10 to 15 counselling sessions; and all participants who resumed smoking before week 24 and were still motivated to quit at week 24 were offered a second, 12-week, open-label treatment phase with varenicline (Mercie 2018).

Tobacco use cessation outcomes

A pooled estimate combining the two studies suggests that more people successfully quit smoking in the varenicline group compared with placebo (RR 1.95, 95% CI 1.05 to 3.62; moderate-certainty evidence), with no evidence of heterogeneity (I^2 = 0%; Analysis 5.1; Summary of findings 2). Abstinence in the control group was 7% (14/215) and in the intervention group it was 13% (27/212). Although these results are only from two studies with a total of 427 participants, there is a good chance that further studies would support this observed benefit when we consider how the CIs incorporate huge benefit and how effective varenicline is in the general population.

Adverse events

A pooled estimate combining the two studies suggests no difference between varenicline and placebo in the proportion of participants experiencing AEs when used for smoking cessation among PLWH who smoke (RR 0.90, 95% CI 0.60 to 1.33), with moderate heterogeneity (I^2 = 58%; Analysis 5.2). The proportion of participants experiencing adverse events in the control group was 49% (105/215) and in the intervention group was 46% (97/212).

Serious adverse events

When considering the proportion of participants experiencing SAEs, the pooled estimate combining the two studies shows that there is insufficient evidence to show any difference between varenicline and placebo (RR 1.14, 95% CI 0.58 to 2.22; low-certainty evidence), with no evidence of heterogeneity (I^2 = 0%) (Analysis 5.3; Summary of findings 2). The proportion of participants experiencing SAEs in the control group was 7% (15/215) and in the intervention group it was 8% (17/212). Mercie 2018 reported that most AEs were grade 1 or 2 and were mainly gastrointestinal and psychiatric disorders. Twenty-three participants in the varenicline group and 22 in the placebo group reported at least one grade 3 or 4 clinical AE; whilst seven participants in each group had at least one grade 3 or 4 drug-related AE.

HIV viral load

Mercie 2018 did not report a formal comparison between the intervention and control. However, they highlighted that for both groups, the mean HIV-1 RNA load remained stable between 1.8 and 2.0 log10 copies per mL; 88% (57/65) in the varenicline group and 91% (67/74) in the placebo group had 50 copies per mL or less at week 48.

CD4 count

Again, Mercie 2018 did not report a formal comparison between the intervention and control. They, however, reported mean CD4 counts of 612 cells per µL (244) in the varenicline group and 685 cells per µL (277) in the placebo group at week 48.

No studies in this group measured the other outcomes (i.e. quit attempts, the proportion of patients who are tobacco users at the time of a consultation who receive a tobacco use cessation intervention, quality of life or incidence of opportunistic infections).

Varenicline versus NRT

The one study (200 participants) in this group provided all participants with brief guideline-based counselling on alcohol and smoking, and tested the addition of varenicline against the addition of NRT (Tindle 2022). The varenicline group also received NRT placebo, whilst the NRT group received varenicline placebo.

Tobacco use cessation outcomes

Results from this study did not find evidence of a difference in smoking abstinence between the varenicline group and the NRT group (RR 0.93, 95% CI 0.48 to 1.83; very-low certainty evidence; Analysis 6.1; Summary of findings 2). Abstinence was achieved by 14% (14/100) of participants in the varenicline group and 15% (15/100) in the NRT group.

The other relevant outcomes (i.e. AEs, SAEs, quit attempts, the proportion of patients who are tobacco users at the time of a consultation who receive a tobacco use cessation intervention, quality of life, HIV outcomes (viral load, CD4 count) and incidence of opportunistic infections) were not measured in this study.

Cytisine versus NRT

The one study (200 participants) in this group provided all participants with brief guideline-based counselling on alcohol and smoking, and tested the addition of cytisine against the addition of NRT (Tindle 2022). The cytisine group also received NRT placebo, whilst the NRT group received cytisine placebo.

Tobacco use cessation outcomes

Results from this study did not find evidence of a difference in abstinence between the cytisine group and the NRT group (RR 1.18, 95% CI 0.66 to 2.11; very-low certainty evidence; Analysis 7.1; Summary of findings 2). Abstinence was achieved by 20% (20/100) of participants in the cytisine group and 17% (17/100) in the NRT group.

The other relevant outcomes (i.e. AEs, SAEs, quit attempts, the proportion of patients who are tobacco users at the time of a consultation who receive a tobacco use cessation intervention, quality of life, HIV outcomes (viral load, CD4 count) and incidence of opportunistic infections) were not measured in this study.

Studies testing intervention delivery modalities

A small study by Kim 2018 (49 participants) compared the delivery of behavioural support for smoking cessation by telephone voice calls to delivery by telephone video calls. The behavioural support comprised eight, weekly individual counselling sessions whose content was drawn from a cognitive behavioural therapy foundation. Both groups also received an eight-week supply of nicotine patches.

Tobacco use cessation outcomes

Those in the video arm were more likely to maintain smoking abstinence over the six-month follow-up period (RR 7.68, 95% CI 1.04 to 56.86; Analysis 8.1). Of the two groups, 32% (8/25) of participants in the video group achieved abstinence, whilst this was 4% (1/24) in the voice group.

No other relevant outcomes (i.e. AEs, SAEs, quit attempts, the proportion of patients who are tobacco users at the time of a consultation who receive a tobacco use cessation intervention, quality of life, HIV outcomes (viral load, CD4 count) and incidence of opportunistic infections), were measured.

System-change interventions

The two outcomes, tobacco cessation and receipt of a tobacco cessation intervention at consultation, reported in the two system-change intervention studies are summarised below. The other outcomes of interest (i.e. AEs, SAEs, quit attempts, quality of life, HIV outcomes (viral load, CD4 count) and incidence of opportunistic infections) were not measured in these studies.

Tobacco use cessation outcomes

Huber 2012 did not report data in the format required for our analysis. However, the study authors reported that structured

training of all HIV care physicians in smoking cessation counselling led to increased smoking cessation (odds ratio (OR) 1.23, 95% CI 1.07 to 1.42; P = 0.004), and fewer relapses of smoking (OR 0.75, 95% CI 0.61 to 0.92; P = 0.007), compared with participants at other institutions where the physicians did not receive the training.

For Mussulman 2018, while the point estimate suggested a benefit for smoking cessation from warm handoff compared with fax referral, confidence intervals were very wide and included the potential for large or no benefit (RR 3.18, 95% CI 0.76 to 13.39; very low-certainty evidence; Analysis 9.1; Summary of findings 1). Of the two groups, 45% (5/11) of participants in the warm handoff group achieved abstinence compared to 14% (2/14) in the fax referral group.

Receipt of a tobacco use cessation intervention at consultation

Huber 2012 reported that smoking cessation counselling was carried out in 1888 of 2374 visits (80%) for current smokers at the intervention centre where physicians were trained. For the control centres, in addition to standard care, described as frequent short counselling, half of the institutions reported offering 'detailed counselling' if indicated, and around half reported handing out information booklets. Also, institutions reported using nicotine substitution, or prescribing bupropion or varenicline in some patients. All institutions reported referring patients to specialised addiction treatment institutions if the patient so wished.

Mussulman 2018 reported no evidence of effect for warm handoff versus fax referral on receipt of inpatient cessation medications (4.2% versus 20.8% respectively, P = 0.17); use of cessation medication (4.0% versus 12.0% respectively, P = 0.6) and enrolment in the quitline (100% versus 71.5% respectively, P = 0.18). Quitline counselling completion was also similar between groups.

Tailored versus non-tailored interventions

We could not address our second objective, which was to compare the benefits and harms of individual-/group-level and system-change interventions for tobacco use cessation that are tailored to the needs of PLWH with that of non-tailored cessation interventions. This was because the majority of the interventions were tailored.

Funnel plot

We did not create a funnel plot for any outcomes for any study groups because fewer than 10 studies were included.

Subgroup analyses

We did not perform any of the planned subgroup analyses due to having too few studies.

DISCUSSION

Summary of main results

This systematic review provides evidence from 17 studies with a total of 9959 participants: 15 of these studies evaluated individual-/group-level interventions delivered directly to PLWH who use tobacco. All 17 studies focused on cigarette smoking cessation. Seven of these 15 studies with a total of 2314 participants contributed to the meta-analysis comparing behavioural support to brief advice or no intervention, whilst two with a total of 427 participants contributed to that comparing varenicline to placebo. Two studies compared different types of behavioural support against each other (355 participants). Single studies assessed behavioural support plus NRT versus brief advice (15 participants), behavioural support plus NRT versus behavioural support alone (560 participants), and different intervention delivery modalities (49 participants). One study evaluated varenicline versus NRT and cytisine versus NRT (400 participants). Two studies evaluated system-change interventions (5833 participants).

Individual-/group-level interventions

There was no evidence of intervention effect for behavioural support versus brief advice or no intervention on tobacco use cessation outcomes (low-certainty evidence; Summary of findings 1). Only one of the seven studies in this group reported promising results, suggesting that real-time social support through an online social network may result in an increase in the chances of abstinence and quit attempts (Shuter 2022). Comparisons between different kinds of behavioural support included only two studies, and one of these suggests that targeting smoking cessation, anxiety, and depression simultaneously may result in larger increases in the chances of smoking cessation among PLWH than targeting smoking cessation alone (O'Cleirigh 2018). In the other study, there was no difference in intervention effects between more and less intensive behavioural support with respect to abstinence or quit attempts (Stanton 2015).

There was no evidence of intervention effects for NRT when given in combination with behavioural support over brief advice or behavioural support alone (very low- to low-certainty evidence; Summary of findings 2; NCT01484340; Wewers 2000). However, results from one study suggest no difference in the chances of experiencing SAEs with NRT compared to not receiving NRT (low-certainty evidence; NCT01484340). We also identified one study that found no evidence of intervention effect for cytisine over NRT (very low-certainty evidence; Summary of findings 2; Tindle 2022). The one study comparing intervention delivery modalities found that telephone video calls increased the chances of continuous smoking abstinence when compared to telephone voice calls (Kim 2018).

From the meta-analyses, we found that varenicline likely results in a larger increase in the chance of achieving continuous smoking abstinence compared to a placebo. The pooled estimate indicates that varenicline can increase cessation success by 5% to 362% when compared to placebo (moderate-certainty evidence; Summary of findings 2; Ashare 2019; Mercie 2018). The proportion of participants experiencing AEs or SAEs was similar between varenicline and placebo, suggesting a similar risk of harms between the two groups (low-certainty evidence). Thus, there is no evidence to suggest that varenicline works differently or has a different profile in this population as opposed to the general population, where there is a much stronger evidence base showing that, compared to no pharmacotherapy, varenicline increases the chances of successful long-term smoking cessation between two- and three-fold (Livingstone-Banks 2023). When compared to NRT, however, we identified one study which found no evidence of intervention effect for varenicline over NRT (very low-certainty evidence; Summary of findings 2; Tindle 2022).

System-change interventions

Evidence from one study showed no evidence of intervention effect of hospital staff handing off PLWH who smoke to smoking cessation

services by calling the quitline when compared to fax referral to the quitline (Mussulman 2018). Another study suggested that structured training of HIV care physicians in smoking cessation counselling could lead to increased smoking cessation and fewer relapses of smoking (Huber 2012), although we judged the overall risk of bias as serious. The study was a non-randomised natural experiment that compared one intervention site to the rest of the sites. It did not assess the effects of the intervention on receipt of tobacco cessation interventions at consultation (Huber 2012). On the other hand, Mussulman 2018 found no evidence of an effect of an intervention where hospital staff handed off PLWH who smoke to smoking cessation services by calling the quitline, on receipt of tobacco cessation interventions at consultation.

Tailored versus non-tailored interventions

As noted, we were unable to assess one of the original objectives, that is, comparing the benefits and harms of individual-/group-level and system-change interventions for tobacco cessation that are tailored to the needs of PLWH with that of non-tailored cessation interventions. This was because most of the included studies provided tailored interventions.

Subgroup analyses

We did not perform any of the planned subgroup analyses due to the small numbers of studies.

Risk of bias

We judged the majority of RCTs to be at low risk of selection bias in random allocation (63%), detection bias (94%), attrition bias (63%) and reporting bias (81%). We assessed only four RCTs for the risk of performance bias, and three of these (75%) we judged as low risk. The proportion judged as low risk of selection bias on allocation concealment was 44%. We did not identify any studies as having other sources of bias.

Overall completeness and applicability of evidence

The literature on this topic is still dominated by studies conducted in the USA (Ashare 2019; Humfleet 2013; Kim 2018; Lloyd-Richardson 2009; Mussulman 2018; O'Cleirigh 2018; Shelley 2015; Shuter 2022; Stanton 2015; Stanton 2020; Vidrine 2012; Wewers 2000), with a few studies in Europe (Gryaznov 2020; Huber 2012; Mercie 2018; Tindle 2022), and only one study in sub-Saharan Africa (NCT01484340), where the majority of PLWH live (UNAIDS 2023). There are health-system and socioeconomic differences between the USA, Europe, sub-Saharan Africa and other parts of the world that limit the generalisability of these results. The trend is similar for ongoing studies, with 19 out of the 25 studies based in the USA, two in Canada, and one each in Kenya, Botswana, China and Vietnam.

We identified a good number of RCTs of individual-/group-level interventions delivered directly to PLWH who use tobacco. However, for system-change interventions, there was only one RCT and one non-randomised study. As a result, most studies were on PLWH who smoke, rather than directed at other relevant populations such as staff working in healthcare settings and providing care to PLWH. This is besides the opportunities to support tobacco cessation presented by the frequent contact PLWH have with health professionals. In addition, all the included studies focused on PLWH who smoke cigarettes, and none focused on the use of any other tobacco products, although they are also harmful to health.

Individual-/group-level interventions delivered directly to PLWH who use tobacco were dominated by evaluations of behavioural-support interventions (10 studies), with only five studies evaluating pharmacotherapy (NRT, varenicline and cytisine). None of the studies evaluated bupropion. We also did not identify any eligible study evaluating e-cigarettes as cessation aids, or any tobacco cessation induction trials. There is a need for more pharmacotherapy trials in this population considering their benefits for smoking cessation in the general population. For system-change intervention studies, one study was on referral and the other on training health workers; we did not identify any eligible studies of other interventions, for example, those aimed at increasing the identification of PLWH who use tobacco, or documentation of tobacco use status among PLWH.

The primary outcome of all the included studies was smoking abstinence. Only a very few studies measured the other outcomes of interest, that is, quit attempts (two studies), AEs (one study), SAEs (two studies), HIV viral load (one study) and CD4 count (one study). Where HIV viral load and CD4 counts were reported, there was not enough information to enable comparisons between groups. None of the individual-/group-level interventions measured the proportion of patients who are tobacco users at the time of a consultation who receive a tobacco use cessation intervention. Although both of the system-change intervention studies measured this outcome (i.e. receipt of a tobacco use cessation intervention at consultation among tobacco users), only one had enough information to enable comparisons between groups. None of the studies measured quality of life outcomes or incidents of opportunistic infections. Further research needs to strengthen evidence on intervention effects on these outcomes. This is particularly important in order to address any concerns that healthcare professionals might have about side effects and potential interactions between cessation pharmacotherapies and ART medicines.

We had planned to use funnel plots to test for publication bias, but were unable to do this because none of our analyses contained 10 or more studies. Because of this, we cannot rule out the potential for publication bias.

Quality of the evidence

For the primary measure of benefit, tobacco use cessation at a minimum of six months after the start of the intervention, we judged the certainty of evidence to be low for the comparison behavioural support versus brief advice or no intervention (Summary of findings 1). For this comparison, whilst there was some heterogeneity in whether the behavioural support was provided in conjunction with pharmacotherapy, statistical heterogeneity was low and there was no evidence of subgroup differences. We therefore did not downgrade the certainty of evidence for this reason. We did, however, downgrade two levels for imprecision because the confidence intervals incorporated both clinically significant benefits and clinically significant harms.

For system-change interventions, we judged the certainty of evidence for the comparison between warm handoff versus fax referral as very low after downgrading two levels for imprecision (the confidence intervals incorporated both clinically significant

benefits and clinically significant harms); and one level because of the high risk of bias judgement for the sole RCT in this comparison (Summary of findings 1).

This was the same for the comparisons between behavioural support plus NRT and brief advice, varenicline and NRT, and cytisine and NRT (Summary of findings 2). We judged the certainty of the evidence for varenicline versus placebo as moderate after being downgraded one level because the confidence intervals incorporated no clinical difference as well as clinically significant harm (Summary of findings 2). For the comparison between behavioural support plus NRT and behavioural support alone, the certainty of evidence was low: we downgraded it by two levels for imprecision, as the confidence intervals incorporated both clinically significant benefits and clinically significant harms.

Data for SAEs, which was a primary measure of harm, were available for only two comparisons; behavioural support plus NRT versus behavioural support alone, and varenicline versus placebo. For both comparisons, the certainty of evidence was low: we downgraded it by two levels for imprecision, as the confidence intervals incorporated both clinically significant benefits and clinically significant harms (Summary of findings 2).

Potential biases in the review process

We followed standard Cochrane methods that involved a robust review process. Our searches were extensive and included trials registries in order to capture ongoing studies. However, there is still a possibility that some studies might have been missed. Unfortunately, we were not able to investigate publication bias for any of the outcomes for all study groupings as there were not enough studies. We grouped the studies according to the intervention being evaluated and the comparison made. Although this resulted in small numbers of studies in each group, it helped elucidate glaring gaps on the types of interventions that have been evaluated in this population. We have one study evaluating incentivised onsite tobacco use cessation for patients (272 participants) that is awaiting classification because, although it seemed to have been completed, we could not get the full text, and we did not have acces to contact details of the authors (Warner 2020). However, it is unlikely that inclusion of the results from this study would change the interpretation of the current results, as the intervention is different to those that have been reported here.

We appreciate that the currency of the search may be considered a limitation. We revisited and checked all ongoing studies and studies awaiting classification prior to publication, and their status remains unchanged. Seven of the ongoing studies are now marked as complete on the trials registries, but the full results reports are not yet available (Cioe 2021; NCT01800019; NCT02460900; NCT02982772; NCT04808609; NCT05020899; NCT05339659). Therefore, we believe we have included all relevant studies in the review and are confident that the findings are robust.

As is standard for Cochrane reviews, all reports were reviewed and all data were extracted in duplicate in order to reduce bias. We only assessed the risk of performance bias for studies that evaluated pharmacological interventions, and ruled this not applicable for studies that evaluated behavioural interventions as per the standard methods used for Cochrane Tobacco Addiction Review Group cessation reviews (Hartmann-Boyce 2023).

One study reported on HIV viral load and CD4 count, but narratively, with no comparisons between groups (Mercie 2018). We, therefore, also reported these results narratively in the review without making comparisons. In addition, one of the two system-change intervention studies did not report outcome data in the format required for our analysis, and we had to report the results as reported by the study (Huber 2012). We could not compare the benefits and harms of individual-/group-level and system-change interventions for tobacco cessation that are tailored to the needs of PLWH with that of non-tailored cessation interventions because the majority of the interventions were tailored. We did not perform any of the planned subgroup analyses due to the small number of studies.

Agreements and disagreements with other studies or reviews

There are a few differences between this review and the previous Cochrane systematic review (Pool 2016). We focused on outcomes measured at a minimum of six months' follow-up and excluded those that were less than six months. We also included system-change interventions in addition to individual-/group-level interventions delivered directly to PLWH who smoke for tobacco cessation. In addition, for our meta-analysis, we grouped the studies according to the interventions under investigation and the types of comparisons made. By so doing, we were able to show that, whilst there was no evidence of intervention effect for behavioural support over brief advice or no intervention, varenicline is likely to result in an increase in the chances of achieving continuous smoking abstinence compared to placebo.

Our findings differ from those reported by two other reviews, which suggest that behavioural support with or without NRT could increase smoking cessation rates in this group (Keith 2016; Moscou-Jackson 2014). This difference could be due to differences in inclusion and exclusion criteria, such as inclusion of studies with follow-up periods of less than six months, and differences in study groupings where a meta-analysis was conducted. One of the reviews only conducted a narrative synthesis with no meta-analyses (Moscou-Jackson 2014).

In the general population, interventions that combine behavioural support and NRT components have been shown to increase the chances of long-term abstinence when compared to a brief intervention without pharmacotherapy (Hartmann-Boyce 2019; Hartmann-Boyce 2021). In addition, although we found evidence to suggest that varenicline increased the chance of achieving smoking abstinence compared to placebo, the point estimate was lower than that observed in the general population, although there was a significant overlap in confidence intervals (Livingstone-Banks 2023). The reason for this difference could be the significantly fewer studies (two) contributing to the analysis in this review compared to the much larger body of evidence on varenicline in the general population (i.e. 41 studies; Livingstone-Banks 2023). This also applies to the comparison between varenicline and NRT where the one study in this review did not detect a difference in effect, but the general population evidence suggests a risk ratio of 1.25 (95% CI 1.14 to 1.37) in favour of varenicline at six months from 11 studies (Livingstone-Banks 2023). Contrary to our findings from the one study that reported on cytisine versus NRT, the general population systematic review found one study of 1310 people that found a benefit for cytisine at six months (RR 1.43, 95% CI 1.13 to 1.80; Livingstone-Banks 2023).

The following could partly explain a less pronounced effect from interventions combining behavioural support and NRT. Compromised cognitive function, which is highly prevalent among PLWH (Heaton 2015), may lower their chances of quitting and increase the probability of relapse (Etter 2000; Loughead 2015). Alcohol use and mental health difficulties such as stress, anxiety, and depression are also highly prevalent among PLWH (Hitsman 2013; Humfleet 2009; Kinyanda 1998; Krishnan 2018; Leventhal 2015; Nanni 2015; Petrushkin 2005; Thirlway 2021), and are all strongly and positively associated with smoking, difficulties in quitting and high chances of relapse. Addressing smoking, common mental disorders and alcohol use together could increase the chances of quitting smoking in this population. For example, in a small RCT in the USA that followed 24 participants for six months, targeting smoking, anxiety and depression together significantly increased the chances of quitting among smokers diagnosed with HIV (O'Cleirigh 2018).

People with mental health problems have some similarities to PLWH; they use more tobacco than the general population, often consume tobacco alongside drugs or alcohol, and may use tobacco to cope with their symptoms or treatment side effects (Tsoi 2013). In Tsoi and colleagues' review of smoking cessation interventions for people with schizophrenia, they found that, at short-term follow-up, there was evidence in favour of a combined intervention (counselling and NRT) but long-term follow-up failed to detect evidence of a difference between the intervention and control (Tsoi 2013). Their results echo the results of this meta-analysis and could reflect a higher potential for relapse in people with complex chronic diseases and multiple challenges. However, the comparison is limited, as the two populations have distinct differences, both medically and psychosocially.

AUTHORS' CONCLUSIONS

Implications for practice

For individual-/group-level interventions delivered directly to people living with HIV (PLWH) who use tobacco, there is currently no clear evidence to support or refute the use of behavioural support over brief advice or no intervention, one type of behavioural support over another, behavioural support plus nicotine replacement therapy (NRT) over behavioural support and brief advice, varenicline over NRT, or cytisine over NRT for tobacco use cessation in this population. For system-change interventions, there is also no clear evidence to support or refute the training of HIV healthcare workers in the provision of tobacco cessation support, or the use of warm handoff over fax referral, in order to increase tobacco cessation or receipt of tobacco cessation interventions among PLWH who use tobacco. However, the results must be considered in the context of the small number of studies included and the very low- and low-certainty evidence. Further evidence could change this conclusion. On the other hand, compared to placebo, varenicline likely helps PLWH to quit smoking for six months or longer, as we found evidence suggesting a benefit in this population. We did not find evidence of difference in serious adverse event rates between varenicline and placebo, although the certainty of the evidence is low. Across all these interventions, the scarcity of data on effects on adverse events, serious adverse events, HIV viral load, CD4 count and incidence of opportunistic infections further complicates the ability to make meaningful practice conclusions.

Implications for research

Further randomised controlled trials (RCTs) of tobacco cessation interventions in PLWH are needed to ascertain whether differences in results between PLWH and the general population are genuine or because of limitations in the evidence. Particular priority should be given to studies that investigate the effects of behavioural support plus pharmacotherapy or system-change interventions. They should include a large sample size and ensure that follow-up continues for at least six months, and preferably 12 months. Studies should also investigate relapse prevention in PLWH who achieve short-term cessation. This would maximise the probability of short-term success being translated into long-term cessation.

Trials that assess the impact of tailoring and intensity of interventions are also needed. Tobacco consumption may affect HIV treatment response, as such, future studies should also assess HIV outcomes - CD4 count, viral load, and incidence of opportunistic infections. The fact that 12 out of the 17 included studies are based in the USA limits generalisability due to population and health system differences. Further studies should be based in a range of contexts, particularly in low- and middle-income countries with a high burden of both HIV and tobacco consumption.

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The following people conducted the editorial process for this article.

- Sign-off Editor (final editorial decision): Lisa Bero, University of Colorado, Aurora
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Joanne Duffield, Cochrane Central Editorial Service
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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Ashare 2019

Study characteristics	
Methods	Country: USA Design: parallel, 2-group, placebo-controlled RCT Number of centres: 1 (university) Selection: through the university's Infectious Diseases Division, a community-based HIV medical clinic, and advertisements Definition of tobacco user/smoker: report daily smoking
Participants	Number: 179 Average age: 48.6 years Gender: 68.2% male Sexuality: not reported Race/ethnicity: 81.5% African American Average cpd: 11.5 Nicotine dependence: 67% high HSI Inclusion/exclusion criteria follow-up?

Ashare 2019 *(Continued)*

Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **All participants received:** 6 standardised one-on-one, PHS guideline-based smoking cessation counseling sessions; in-person or by telephone; weeks 0, 1, 3, 5, 7, and 9; delivered by trained counsellors. HIV-specific module was included to educate participants about the unique health risks associated with smoking among PLWH. **Intervention:** varenicline was provided at week 0 based on FDA labelling: day 1-day 3 (0.5 mg once daily), day 4–7 (0.5 mg twice daily), and day 8-day 84 (1.0 mg twice daily). **Control:** placebo pills were identical in appearance and dosing regimen.
Outcomes	• Continuous abstinence: week 9 to week 12, 18 and 24 • Validation: eCO; ≤ 8 ppm to confirm abstinence • Adverse events
Notes	Funding: National Institute on Drug Abuse grants (R01 DA033681 and K24 DA045244); the Penn Center for AIDS Research (P30 AI045008) and the Penn Mental Health AIDS Research Center (P30 MH097488) core services and support. Pfizer provided medication and placebo free of charge. Conflict of interest: "Dr Schnoll received medication and placebo free of charge from Pfizer for clinical trials and has provided consultation to Pfizer, GlaxoSmithKline, and Curaleaf. Dr Gross serves on a Pfizer Data and Safety Monitoring Board for a drug unrelated to smoking or HIV. Dr Ashare has an investigator-initiated grant from Novo Nordisk for a drug unrelated to the current study."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised 1:1 by a computer-generated protocol
Allocation concealment (selection bias)	Low risk	Central randomisation: computer-generated protocol provided by the study statistician to the University of Pennsylvania's Investigational Drug Service (IDS), who maintained the supply of varenicline and placebo. As part of this investigator-initiated project, Pfizer provided varenicline and placebo directly to IDS who repackaged the pills into blister packs
Blinding of participants and personnel (performance bias) All outcomes	Low risk	All participants and study personnel, aside from IDS, were blinded from treatment arm allocation throughout the trial.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical verification
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differences between groups
Selective reporting (reporting bias)	Low risk	None identified
Other bias	Low risk	None identified

Gryaznov 2020

Study characteristics	
Methods	Country: Switzerland Design: parallel, 2-group RCT Number of centres: 60 (outpatient clinics, hospitals, and private practices) Selection: recruited from the Swiss HIV Cohort Study Definition of tobacco user/smoker: smoking > 3 cpd
Participants	Number: 81 Average age: 47 years Gender: 84% male Sexuality: at least 51% men who have sex with men; and 33% heterosexual Race/ethnicity: not reported Average cpd: 17 Nicotine dependence: not reported
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **Interventions** • Short smoking cessation advice, voluntary referral to smoking cessation clinics, and NRT at the physician's discretion • CO self-monitoring using the iCO Smokerlyzer, with mobile phone-based feedback; and mobile phone app-based smoking cessation support. Participants were requested to use the personal CO monitor Smokerlyzer daily for the first 4 weeks, twice weekly for the following 4 weeks and once weekly from the beginning of the third month to the end of the trial. The mobile phone app-based smoking cessation support provides advice for quitting, coping with withdrawal symptoms, and relapses. It provides personalised messages that encourage smoking cessation and give advice for behavioural change, options to seek support from friends and family, and a forum for discussing smoking cessation-related issues with peers. **Control:** short smoking cessation advice, voluntary referral to smoking cessation clinics, and NRT at the physician's discretion The short smoking cessation was delivered face-to-face by treatment centre physicians
Outcomes	• Continuous abstinence at 6 months of follow-up: no more than 5 cigarettes since the start of the abstinence period • Validation: in-person CO breath test (with a cut-off in eCO of 7 ppm)
Notes	Funding: "Swiss National Science Foundation (grant #177499), Research Fund of the Swiss Lung Association, Berne (Grant Number 2016-15). Stiftung Institut für klinische Epidemiologie" Conflict of interest: no conflict of interest to disclose

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Random allocation but does not specify how
Allocation concealment (selection bias)	Unclear risk	Not enough information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemical verification

Gryaznov 2020 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 3 participants lost to follow-up
Selective reporting (reporting bias)	Low risk	None identified
Other bias	Low risk	None identified

Huber 2012

Study characteristics	
Methods	Country: Switzerland Design: natural experiment that compared 1 intervention site to the rest of the sites Number of centres: 60 (outpatient clinics, hospitals, and private practices) Selection: recruited from the Swiss HIV Cohort Study Definition of tobacco user/smoker: not specified
Participants	Number: 5808 smokers for smoking cessation and 1953 in relapse analysis Average age: 38 years Gender: 70% male Sexuality: at least 38% men who have sex with men and 37% heterosexual Race/ethnicity: not reported Average cpd: not reported Nicotine dependence: not reported
Interventions	Type of interventions: system-change interventions **Intervention:** physician training plus a physicians' checklist for semi-annual documentation of counselling: standardised, half-day training on smoking cessation for all physicians at the HIV outpatient clinic at the University Hospital Zurich. This training – conducted in a standardised way by trainers of the Swiss Lung Association – included information on identification of smokers, nicotine dependence, nicotine withdrawal-related problems, motivation stages of intended behavioural change of substance-dependent persons according to the Prochaska/Di Clemente transtheoretical model, methods of counselling, and pharmacological support of smoking cessation. At every cohort visit during the intervention period, physicians had to complete a short checklist to document the participants' smoking status, their current motivation level to stop smoking, and physician's support offered at this visit. Support for smoking cessation included short or detailed counselling about problems associated with smoking cessation, information on medication (nicotine, bupropion and varenicline), arranging a follow-up appointment for further discussion about smoking cessation, and, if appropriate, planning a date for smoking cessation. **Control:** usual care. In addition to 'standard care' – 'frequent short counselling', half of the institutions reported offering 'detailed counselling' if indicated, and around half reported handing out information booklets. Also, institutions reported using nicotine substitution, or prescribing bupropion or varenicline in some patients. All institutions reported referring patients to specialised addiction treatment institutions if the patient so wished.
Outcomes	Smoking cessation event: at least 1 follow-up visit with smoking followed by at least 2 consecutive semi-annual follow-up visits without smoking. Measured at 6, 12, 18, 24, and 30 months, and at 3 years No validation
Notes	Funding: "this study was financed in the framework of the Swiss HIV Cohort Study, supported by the Swiss National Science Foundation."

Huber 2012 *(Continued)*

	Conflict of interest: no conflict of interest statement

Humfleet 2013

Study characteristics	
Methods	Country: USA Design: parallel, 3-group RCT Number of centres: 3 (2 community-based programmes and 1 public health facility) Selection: participant self-referral or clinician referral. Postcards and flyers at clinics, letters sent to patients Definition of tobacco user/smoker: self-report smoking most days in a month
Participants	Number: 209 Average age: 45 years Gender: 82% male Sexuality: 62% gay/lesbian, 24.3% straight, 7.4% bisexual Race/ethnicity: 53% white Average cpd: 19.8 Nicotine dependence: mean FTND score 4.9
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **Interventions** • Computer-based intervention: 1 face-to-face orientation meeting of 45-60 min. Six counselling sessions based on CBT, delivered via a website, in addition to message board and 'ask the experts' options on the website. Mean duration on website 30-45 min. 10 weeks of NRT, patch or gum, available to participants who smoked ≥ 5 cpd; dose not stated • Individual counselling: 6 individual, face-to-face sessions based on CBT over 12 weeks. Session duration 40-60 min. NRT as per computer-based intervention group **Control:** one-off, brief, face-to-face meeting with research staff and written reference guide provided. NRT as per the intervention groups Provider of individual counselling: "clinicians with a master's or doctoral degree in social work or psychology and had previous experience in smoking cessation treatment" Tailoring: individual counselling was tailored via focus on impact of smoking on HIV, stress, depression, low social support and HIV-related health issues. The computer-based intervention was described as modelled on individual counselling and therefore assumed to be tailored. Control was not described as tailored
Outcomes	Abstinence: 7-day PPA and sustained abstinence at 12, 24, 26, and 52 weeks following intervention. In individual counselling group TQD was in week 2. TQD is not clearly described for CBI or control groups Validation: PPA outcomes were verified by eCO ≤ 10 ppm, the sustained abstinence outcomes were not biochemically verified
Notes	PPA and sustained abstinence outcomes were measured but sustained outcomes were not described in detail in the published report. The sustained outcome data for meta-analysis were obtained via email communication with the authors. Funding: "this work was supported by NIDA grants (P50-DA09253, R01-DA15791, and R01-DA02538) and California TRDRP grant (15RT-0165)." Conflict of interest: "there are no competing interests to declare for any of the authors."
Risk of bias	

Humfleet 2013 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were "randomized via computer algorithm to one of 3 conditions in 1:1:1 fashion into a parallel group design"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically verified
Incomplete outcome data (attrition bias) All outcomes	Low risk	Proportion of missing participants was evenly balanced between groups
Selective reporting (reporting bias)	High risk	The study was registered on clinicaltrials.gov NCT00297453. The primary outcome measure of smoking cessation was measured by PPA and sustained abstinence, but sustained abstinence results were not reported in full.
Other bias	Low risk	None identified

Kim 2018

Study characteristics	
Methods	Country: USA Design: parallel, 2-group RCT Number of centres: not reported (community setting) Selection: through professional networks of healthcare providers who were working with PLWH and study adverts placed on the free website, Craigslist. Definition of tobacco user/smoker: self-report smoking at least 5 cpd for the past 6 months
Participants	Number: 49 Average age: 51.12 years Gender: 0% male; 100% female Sexuality: not reported Race/ethnicity: 9.52% white; 73.81% black; 16.67% other Average cpd: 14.23 Nicotine dependence: mean FTND score 5.57
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **All participants received:** **Counselling:** 8 weekly individual counselling sessions (10-30 min each). The context was drawn from a CBT foundation, which is guided by Bandura's Social Cognitive Theory. Problem-solving skills and techniques for resisting smoking temptation were emphasised. The counselling sessions were delivered over 8 weeks. **Pharmacotherapy:** an 8-week supply of nicotine patches by 2 postage mailings: first 4-week supplies of 21 mg, followed by 2-week supplies of both 14 and 7 mg. Those who smoked between 5 and 9 cpd received a 4-week supply of 14 mg by the first mail and then a 2-week supply of both 14 and 7 mg by the second mail. • One group received the intervention via telephone-based **video** calls • The second group received the intervention via telephone-based **voice** calls

Kim 2018 *(Continued)*

	The interventions were delivered by 2 therapists. • A tobacco treatment specialist with > 10 years of experience with smoking cessation counseling; and • a graduate student with 20 h of intensive training related to the intervention. Supervision of the student was done weekly during the first 2 months and continued biweekly throughout the study. HIV-tailored: the effects of smoking on people with HIV were highlighted during the first session.
Outcomes	Continuous abstinence: self reported prolonged abstinence, except for the first 2-week grace period measured at 3 and 6 months. Validation: cotinine. Cut off of < 10 ng/mL used
Notes	Just mentions cotinine without specifying the source (e.g. urine/blood). But reads as if it is urine cotinine. Funding: "the study was partially supported by a Joseph P. Healey Research Grant awarded to Drs Kim, Sprague, and DeMarco by the University of Massachusetts (UMass) Boston and the UMass Boston – Dana Farber Harvard Cancer Center U54 Partnership (U54 grant) to Drs Kim and DeMarco." Conflict of interest: "the authors report no conflicts of interest in this work."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers
Allocation concealment (selection bias)	Low risk	Allocation determined through computer-generated random numbers. Participants and research team members did not have any prior knowledge of group allocation until it was determined by a random number along with the corresponding group that was enclosed in a sealed envelope
Blinding of outcome assessment (detection bias) All outcomes	High risk	All follow-up assessments were done by an individual who was not fully blind to the group allocation because she had to assist some participants in installing a video call app. Cotinine tests performed by the participants at home
Incomplete outcome data (attrition bias) All outcomes	High risk	12 participants lost to follow-up in the voice call group compared to 4 in the video call group
Selective reporting (reporting bias)	Low risk	None identified
Other bias	Low risk	None identified

Lloyd-Richardson 2009

Study characteristics

Methods	Country: USA Design: parallel RCT Number of centres: 8 (6 outpatient HIV clinics and 2 primary care centres) Selection: participants were recruited at their clinic

Lloyd-Richardson 2009 *(Continued)*

	Definition of tobacco user/smoker: self-report ≥ 5 cpd
Participants	Number: 444 Average age: 42 years Gender: 63% male Sexuality: not reported Race/ethnicity: 52% white Average cpd: 18.2 Nicotine dependence: mean FTND score 5.9
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **Intervention:** 1 brief advice session, plus 4 face-to-face individual counselling sessions based on MI and a quit day phone call. Duration of each counselling session was 30 min. Participants willing to set a TQD were provided with NRT patches, 8 weeks' duration; dose not described. **Control:** 2 brief advice sessions, delivered face-to-face and self-help written materials. In addition, participants willing to set a TQD received biweekly brief sessions (5 min duration) to reinforce quit effort, check patch side effects and distribute NRT patches. NRT provided as per intervention group Provider: health educator trained in smoking cessation Tailoring: intervention was tailored via an emphasis on the impact on infections and immunity. Control was not tailored for PLWH
Outcomes	Abstinence: 7-day PPA at 2, 4, and 6 months post-enrolment Validation: eCO < 10 ppm
Notes	The published report included percentage abstinence rate only; we calculated the number of participants abstinent as we were unable to obtain these via email correspondence with the study authors. Funding: "this research was supported by grant R01-DA12344-06 from the National Institute of Drug Abuse (R. Niaura, PhD), grant K23-HL069987 from the National Heart, Lung, and Blood Institute (E. Lloyd-Richardson, PhD), grant K07-CA95623 from the National Cancer Institute (C. Stanton, PI), an NIH-funded Transdisciplinary Tobacco Use Research Center (TTURC) Award (P50 CA084719), an NIH-funded Lifespan/Tufts/Brown Center for AIDS Research Award (P30 AI42853), and by the Robert Wood Johnson Foundation." Conflict of interest: no conflict of interest statement

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were then randomized (using block randomization to ensure stratification by gender and level of motivation to quit smoking)"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	“Follow-up assessments were administered by research staff blinded to participant intervention assignment”
Incomplete outcome data (attrition bias) All outcomes	Low risk	Proportion of missing participants is balanced between groups. A missing = smoking assumption was used
Selective reporting (reporting bias)	Low risk	All of the primary outcomes were reported in full. A study protocol was published on clinicaltrials.gov (NCT00551720), the published method and outcomes correlate with the protocol methods and outcomes

Lloyd-Richardson 2009 *(Continued)*

Other bias	Low risk	None identified

Mercie 2018

Study characteristics	
Methods	Country: France Design: parallel, 2-group, double-blind, placebo-controlled RCT Number of centres: 30 (HIV clinics in hospital) Selection: participants approached via the 30 HIV clinics located in French university hospitals or other referral hospitals Definition of tobacco user/smoker: self-report smoking at least 10 cpd for ≥ 1 year
Participants	Number: 248 Average age: 45 years Gender: 83% male Sexuality: at least 53% homosexual/bisexual; and at least 31% heterosexual Race/ethnicity: not reported Average cpd: 20 Nicotine dependence: mean FTND score 5.4
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **All participants received:** counselling (10-15 face-to-face sessions over a year) + all participants who resumed smoking before week 24 and were still motivated to quit at week 24 were offered a second, 12-week, open-label treatment phase with varenicline. • **Intervention:** varenicline titrated to 2 x 0.5 mg twice daily for 12 weeks: 0.5 mg once daily on days 1–3; 0.5 mg twice daily on days 4–7; and 2 x 0.5 mg twice daily from day 8 to week 12. This 12-week treatment period was followed by a planned 13-week period of no pharmacological intervention, with only the smoking cessation counselling. • **Control:** placebo titrated to 2 pills twice daily for 12 weeks The counselling support was delivered by healthcare professionals.
Outcomes	Continuous abstinence: from week 9 to week 48. Was also measured at 2, 4, 6, 9, 12, 18, 24, and 37 weeks Validation: eCO ≤ 10 ppm was used to confirm smoking abstinence. Also measured HIV-1 RNA load; CD4 count and adverse events
Notes	Funding: "the French National Institute for Health and Medical Research (INSERM)–French National Agency for Research on AIDS and Viral Hepatitis (ANRS) and Pfizer." "The funder had no role in study design, collection, analysis, and interpretation of data, writing the report, or in the decision to submit the paper for publication. PM had full access to all data and had final responsibility for the decision to submit for publication" Conflict of interest: "the institution of JR has received funds from Institut National de la Santé et de la Recherche Médicale (Inserm)-France Recherche Nord et sud Sida-hiv Hépatites (ANRS). XD has received grant support from Pfizer. J-MM is a member of scientific advisory boards of Merck laboratories, Gilead, Bristol-Myers Squibb, ViiV Healthcare, and Janssen and has received grant support from Merk laboratories and Gilead. BS has received honoraria for seminars from Merck laboratories, Gilead, and Janssen and support for the IAS 2014 conference from Merck laboratories. The institution of CF and GC has received grant support from Inserm-ANRS and Pfizer. GC has received grant support for International Workshop on HIV and Hepatitis Observational Databases from Gilead, Tibotec-Janssen, Roche, Merck laboratories, Janssen Pharmaceuticals, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline,

Mercie 2018 *(Continued)*

	ViiV Healthcare, Mylan, Abbvie, and Abbott and grant support for ongoing clinical trials of Inserm-ANRS from Gilead, Tibotec-Janssen, Merck laboratories, Boehringer Ingelheim, and Abbott. All other authors declare no competing interests."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation (1:1) was done centrally via electronic case report software
Allocation concealment (selection bias)	Low risk	Only the trial statistician (JA) had access to the randomisation list during the trial.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and investigators remained masked to treatment groups until the database lock (after week 48), and therefore did not know to which group the participant was originally assigned
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Abstinence biochemically validated
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition over 50% in both study arms
Selective reporting (reporting bias)	Low risk	None identified
Other bias	Low risk	None identified

Mussulman 2018

Study characteristics

Methods	Country: USA Design: parallel, 2-group RCT Number of centres: 1 (hospital) Selection: approached all patients listed on daily lists of hospitalised patients with a diagnosis of HIV-positive/AIDS Definition of tobacco user/smoker: smoked at least 1 cigarette in the past 30 days
Participants	Number: 25 Average age: 47.7 years Gender: 76% male Sexuality: not reported Race/ethnicity: 48% African American Average cpd: 16.8 Nicotine dependence: 40% were heavy smokers (heaviness of smoking index ≥ 4); most (83.3%) smoked within 30 min of waking
Interventions	Type of interventions: system-change interventions **All participants received:** standard cessation brochure with information and resources for quitting smoking; quitline

Mussulman 2018 *(Continued)*

	Intervention: warm handoff during the initial brief intervention, UKanQuit staff assessed withdrawal, adjusted NRT to ensure patient comfort, and described warm handoff procedures. UKanQuit staff then performed the handoff by calling the quitline, notifying the quitline that an inpatient was on the line, transferring the call to the patients' mobile or bedside hospital phone for enrollment and an initial counseling session, and then leaving the room. After the quitline session, the counsellor checked back with the patient to follow up on decisions made during the counselling session, such as arranging for medication scripts on discharge. **Control:** fax referral- standard hospital screening and intervention procedures: • assessing withdrawal; • adjusting inpatient NRT to enhance patient comfort; and • providing assistance in quitting, which included developing a quit plan and arranging medication prescriptions on discharge. Staff fax referred patients to the quitline on the day they were discharged from the hospital.
Outcomes	7-day PPA at 1 and 6 months Validation: salivary cotinine (< 15 ng/mL)
Notes	Also reported: • receipt of inpatient cessation medications; • use of cessation medication post-discharge; • enrolment in the quitline; and • quitline counselling completion Funding: "funding for this study was provided by National Heart, Lung, and Blood Institute (NHLBI) grants (U01 HL105232-01; 3U01HL105232-03S1). NHLBI had no role in the study design, collection, analysis or interpretation of the data, writing the manuscript, or the decision to submit the paper for publication." Conflict of interest: "all authors declare they have no conflicts of interest."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random assignment via a tablet computer
Allocation concealment (selection bias)	Unclear risk	Random assignment via a tablet computer
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Follow-up assessments conducted by research assistants blinded to study allocation; also biochemical verification of primary outcome
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used ITT
Selective reporting (reporting bias)	Low risk	None identified
Other bias	Low risk	None identified

NCT01484340

Study characteristics	
Methods	Country: South Africa Design: parallel, 2-group RCT Number of centres: 1 (community health centre) Selection: not reported Definition of tobacco user/smoker: current, daily smoker (biochemically verified via a positive result on the SmokeScreen® test from GFC Diagnostics Ltd
Participants	Number: 560 Average age: 37 years Gender: 78% male Sexuality: not reported Race/ethnicity: 99.5% Black African Average cpd: 10 Nicotine dependence: not reported
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **All participants received:** advice to quit smoking and self-help materials from the study interventionist in a standardised fashion (intensive anti-smoking counselling). Intensive Counseling: the advice to quit smoking message followed National Cancer Institute's 5A's model for smoking cessation counselling. This is a simple smoking cessation counselling strategy with 5 discrete components. 1. Ask about smoking at every opportunity 2. Advise the patient to quit smoking 3. Assess readiness to quit 4. Assist the patient in quitting, and 5. Arrange follow-up The intervention group also received nicotine patches including instruction on the proper use of the nicotine patch (i.e. placement, use of 1 patch a day, the importance of not smoking while using the patch, and tapering of patches). The nicotine patches were given in 3 phases: • 2 weeks of patches at enrollment • 6 weeks of patches at 2-week follow-up visit • 2 weeks of patches at 2-month follow-up visit This schedule covered the entire 10-week course of therapy as per label instructions: 6 weeks at 21 mg; 2 weeks at 14 mg; and 2 weeks at 7 mg
Outcomes	Smoking status using a point-of-care test for measuring CO; or smoking status, or both, using a point-of-care test for measuring cotinine at 2, 6 and 12 months Validation: eCO (≤ 7 ppm); cotinine (< 0.4 µg/mL) Serious adverse events All-cause mortality
Notes	Funding: National Institute on Drug Abuse at the National Institutes of Health (5R01DA030276) and the Johns Hopkins University Center for Global Health Conflict of interest: none declared

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

NCT01484340 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	No details available
Allocation concealment (selection bias)	Unclear risk	No details available
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically verified
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details available
Selective reporting (reporting bias)	Unclear risk	No details available
Other bias	Low risk	None identified

O'Cleirigh 2018

Study characteristics	
Methods	Country: USA Design: parallel, 2-group RCT Number of centres: not reported (primary care clinics; hospital) Selection: providers told potentially eligible patients about the study and offered them the study co-ordinator's contact information Definition of tobacco user/smoker: smoking at least 5 cpd
Participants	Number: 53 Average age: 50.5 years Gender: 84.9% male Sexuality: not reported Race/ethnicity: 86.8% non-Hispanic Average cpd in past week: 14.83 in intervention and 15.39 in the control arm Nicotine dependence: moderate nicotine dependence (FTND: mean (SD) = 5.9 (1.93))
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **All participants received:** • 60-min psychoeducation session involving providing information about the negative health consequences of smoking in the context of HIV, basic strategies for quitting, and details on the transdermal NRT patch. Participants selected their quit date 6 weeks from the date of session 1. • NRT- transdermal nicotine patch for 8 weeks **Intervention:** hybrid cognitive behavioural therapy targetting smoking cessation, anxiety, and depression simultaneously; the treatment includes 6 modules (treatment rationale, education, cognitive restructuring, exposure, problem-solving, and relapse prevention) that are delivered across 9 x 60-min sessions; 1 session every week. In each session, curricular content focuses on managing one's health

O'Cleirigh 2018 *(Continued)*

	in the context of HIV. The intervention was delivered by doctoral-level clinical psychology interns and postdoctoral fellows; individual, face-to-face. Tailoring: in each session, curricular content focuses on managing one's health in the context of HIV. **Control:** enhanced standard smoking intervention comprising 4 post-quit 10-min sessions, stretched over 9 weeks, delivered by the study co-ordinator or research associate. During these sessions, participants reported on their smoking during the previous week and were provided with NRT for the coming week. If participants were abstinent during the past week, they were praised, and strategies for managing nicotine withdrawal were discussed. If participants were not abstinent during the past week, they were encouraged to select another quit date, and preparation for quitting was briefly discussed. Delivered by study co-ordinator or research associate; individual, face-to-face
Outcomes	7 day ppa: no smoking, not even a puff, in the 7 days before any assessment using timeline follow-back at 1, 2, 4 and 6 months Validation: eCO (≤ 4 ppm)
Notes	Funding: "supported by grant R34 DA031038-01 award to the first 3 authors by the National Institute on Drug Abuse (NIDA)" Conflict of interest: "J.A.J.S. has received compensation from Microtransponder, Inc., and Aptinyx, Inc. for consulting. The remaining authors have no conflicts of interests to disclose."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	A randomisation chart was created before the study's start. Block randomisation in blocks of 4 by study co-ordinator.
Allocation concealment (selection bias)	Low risk	The randomisation chart was secured on a password-protected document accessible only by the study co-ordinator and the Principal Investigator. Assignment to study condition was concealed from participants and study clinicians until the end of session 1.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The Independent Assessors for the study were doctoral-level clinical psychologists who were blinded to randomisation arm and to detailed study aims.
Incomplete outcome data (attrition bias) All outcomes	High risk	50% dropped out in the treatment group (QUIT) and 22% in the control (ETAU) - the difference between groups was significant. ITT used for analysis though.
Selective reporting (reporting bias)	Low risk	None identified
Other bias	Low risk	None identified

Shelley 2015

Study characteristics

Methods	Country: USA Design: paralell RCT Number of centres: 3 (HIV care centres at a hospital) Selection: participants were recruited from HIV care centres, willingness to quit within the next 2 weeks was required for inclusion

Shelley 2015 *(Continued)*

	Definition of tobacco user/smoker: self-reporting smoking at least 5 cpd
Participants	Number: 158 Participant characteristics are for 127 participants (outcome data are for all 158 participants) Average age: 50 years Gender: 84% male Sexuality: not reported Race/Ethnicity: 48% black Average cpd: 15 Nicotine dependence: not reported
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **Intervention 1:** text messages, adherence-focused, twice-daily text messages. 12 weeks of varenicline. Based on Information Motivation Behaviour model **Intervention 2:** Adherence Behavioural Therapy, adherence-focused, twice-daily text messages, plus 7 sessions of telephone counselling. Planned duration of call: 20-30 min. Based on Information Motivation Behaviour model. 12 weeks of varenicline **Control/standard care:** 12 weeks of varenicline, dose and frequency not reported. Information sheet and State Quitline number provided. Participants in intervention groups also received control Provider: trained counsellors (Masters level) Tailoring: text messages were tailored through conveying information considered particularly relevant to PLWH, but did not use the terms HIV/AIDS to ensure confidentiality. Adherence Behavioural Therapy intervention discussed the effects of smoking on HIV and focused on specific barriers for PLWH. The self-help information sheet given as standard care was tailored to PLWH.
Outcomes	Abstinence: 7-day PPA at weeks 1, 4, 8, 12, and 24 from start of treatment Validation: eCO < 8 ppm
Notes	The study was registered on clinicaltrials.gov NCT01898195 In published reports, 1-month per protocol outcomes were reported. 24-week ITT outcomes were obtained following correspondence with the author. Funding: NIDA (15R34DA031636-02) and Centre for Drug and HIV Research (CDUHR-P30 DA011041) Conflicts of interest: Pfizer provided study medication. No other conflict of interest declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"...participants were randomly assigned to one of two treatment conditions" but sequence generation not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically verified
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Outcome assessed by self-report and eCO. Proportion of missing participants not described per group. Overall, insufficiently described to permit judgement

Shelley 2015 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	Overall, insufficiently described to permit judgement
Other bias	Low risk	None identified

Shuter 2022

Study characteristics	
Methods	Country: USA Design: parallel, 2-group RCT Number of centres: 2 (urban HIV care sites) Selection: through provider referral from the 2 sites, by direct contact in the clinics' waiting areas and by self-referral in response to flyers distributed locally Definition of tobacco user/smoker: current cigarette smoker (defined as responding in the affirmative to "Have you smoked at least 100 cigarettes in your entire life?" AND "Have you smoked cigarettes (even a puff) in the last 7 days, including today?")
Participants	Number: 512 Average age: 50.47 years in intervention and 49.95 in the control condition Gender: 57.3% male Sexuality: not reported Race/ethnicity: 82.6% black Average cpd: 11.3 intervention condition; 11.8 control condition Nicotine dependence: modified FTND: high (intervention: 28 (11.0%), control: 19 (7.6%)); low (intervention: 45 (17.7%), control: 46 (18.4%)); low/moderate (intervention: 76 (29.9%), control: 60 (24.0%)); moderate (intervention: 105 (41.3%), control: 125 (50.0%))
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **All participants received:** all trial participants were offered a 12-week course of nicotine patches dosed according to average cpd. **Intervention:** Positively Smoke Free on the Web (PSFW+), a multimodal platform, interactive web intervention hosted within an online social network to support quitting among PWH who smoke. PSFW + comprised didactic web content and/or videos and offered a flexible schedule, that is, participants could select and reset the quit day of their choice, view any of the lessons at any time, and access an online community. In addition, 8 x 5–10-min video sessions were available for viewing that were intended to correspond one-to-one with the 8 lessons. They recruited seed users (current or former PLWH smokers from clinical sites) to be part of the study team before participant recruitment. Their role was to foster cessation-related discussions, respond on the site to comments within 24 h, and encourage a sense of community between and among study participants. Delivered over 42 days (roughly 1 per week). **Control:** attention-matched web-based control intervention (American Heart Association Getting Healthy online programme (AHA)). AHA is a health-promotion intervention targeting cardiovascular health and fitness. It has a welcome page and 7 online modules, including 1 on smoking cessation. The other 6 topics are healthy diet, exercise, blood pressure control, blood sugar control, cholesterol, and weight management. The website does not include an online community.
Outcomes	• 7-day point abstinence was determined based on a negative answer to the question, "Have you smoked a cigarette, even a single puff, in the past 7 days?" along with biochemical verification. At 4 weeks, 12 weeks and 6 months. Validation: eCO measurement using the piCO+ Smokerlyzer (coVita); cut-off < 10 ppm • Quit attempts • 30-day PPA • Nicotine patch use

Shuter 2022 *(Continued)*

	• Intervention utilisation • The mean number of active days on the web-based platform
Notes	Funding: "supported by awards from R01CA192954, the National Institutes of Health (NIH)/National Cancer Institute (NCI), and by the Einstein-Rockefeller- CUNY Center for AIDS Research (P30-AI124414), which is supported by the following NIH cofunding and participating institutes and centers: NIAID, NCI, NICHD, NHBL, NIDA, NIMH, NIA, FIC, and OAR." Conflict of interest: "the authors have no conflicts of interest to disclose."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Stratified block randomisation (allocation (1:1)) to PSFW+ or AHA. Randomisation was stratified on study site, sex at birth, and educational level. Block sizes were randomly chosen from the set (4, 6, and 8). Randomisation was centralised with an independent data manager who generated and uploaded the randomisation sequence onto a secure server at the Albert Einstein College of Medicine.
Allocation concealment (selection bias)	Low risk	Randomisation was centralised with an independent data manager who generated and uploaded the randomisation sequence onto a secure server at the Albert Einstein College of Medicine.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes assessors and investigators were blinded to group assignments
Incomplete outcome data (attrition bias) All outcomes	Low risk	About 25% loss to follow-up in both groups; ITT used assuming participants lost to follow-up were non-abstinent
Selective reporting (reporting bias)	Low risk	None identified
Other bias	Low risk	None identified

Stanton 2015

Study characteristics

Methods	Country: USA Design: parallel RCT Number of centres: 9 (immunology clinics) Selection: clinician referral from immunology clinics Definition of tobacco user/smoker: self-report smoking cigarettes in the past 7 days
Participants	Number: 302 Average age: 45 years Gender: 64% male Sexuality: not reported Race/ethnicity: 100% Latino (being Latino was required for inclusion) Average cpd: not reported Nicotine dependence: not reported
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke

Stanton 2015 *(Continued)*

	Intervention: as per control plus 2 additional face-to-face individual counselling sessions (average duration of session 1: 62 min) and 2 additional 10-min phone calls, provided by health educator. All sessions culturally tailored to Latino. Option to bring a 'support buddy', culturally sensitive written materials and videos. If willing to set a TQD received NRT for 8 weeks, dose according to smoking level **Control:** physician brief advice, plus 2 face-to-face individual counselling sessions and 1 quit day phone call (10 min), and written materials. NRT as per intervention Provider: health educator "at least Masters level professionals (or had equivalent years of clinical research experience) and were trained on the implementation of the manual driven interventions" Tailoring: the intervention was tailored being both a PLWH and a Latino, emphasis on the specific health consequences of smoking on HIV. Control not tailored to PLWH or Latino
Outcomes	Abstinence: 7-day PPA at 6 and 12 months post-intervention Validation: eCO < 10 ppm
Notes	Additional data and study design details were obtained via email communication with the study authors ahead of full report publication. Funding: "this work was supported by awards from the National Institute on Drug Abuse (R01DA018079), the National Cancer Institute (K07CA091831; P30CA051008), and the National Institute Of Allergy And Infectious Diseases (P30AI042853). This research has been facilitated by the infrastructure and resources provided by the Lifespan/Tufts/Brown Center for AIDS Research. It was also supported by the Clinical Core of the Center for AIDS Research at the Albert Einstein College of Medicine and Montefiore Medical Center funded by the National Institutes of Health (Grant # AI-51519).The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Health." Conflict of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised "using an urn randomisation procedure" and stratified by gender
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically verified
Incomplete outcome data (attrition bias) All outcomes	Low risk	The distribution of missing participants was balanced between groups (54 from control group, 68 from intervention group). Missing data imputed as missing = smoking
Selective reporting (reporting bias)	Low risk	The study was registered on clinicaltrials.gov NCT00503230 and all primary outcomes were reported in full
Other bias	Low risk	None identified

Stanton 2020

Study characteristics

Methods	Country: USA

Stanton 2020 *(Continued)*

	Design: parallel, 2-group RCT Number of centres: 3 (2 medical/healthcare centres and 1 hospital) Selection: by referral from their primary care providers, direct invitation from the clinic waiting rooms, and self-referral in response to fliers Definition of tobacco user/smoker: current tobacco smoking, defined as an affirmative response to "During the past 5 days, have you used any product containing nicotine including cigarettes, pipes or cigars?"
Participants	Number: 442 Average age: 50.8 years standard care; 50.3 years intervention Gender: 53.2% male Sexuality: not directly reported, HIV risk group was 'same-sex contact' for 25.7% and 24.3%, and 'heterosexual contact' for 51.8% and 58.7% for the control and intervention groups respectively Race/ethnicity: 66.2% black/African American in control, and 65.6% for intervention Average number cpd: 11.2 for the control and 9.7 for the intervention group Nicotine dependence: mean FTND score 4.91 in the control group, 4.60 in the intervention group
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **All participants received:** nicotine patches, 12-week supply **Intervention:** 'Positively Smoke Free' group therapy modelled after the programme described in the Tobacco Dependence Treatment Handbook and based upon Social Cognitive Theory principles. Eight, 90-min sessions delivered in a group, face-to-face over 42 days. Sessions are led by a professional peer pair of group leaders, both of whom completed tobacco treatment specialist training and certification. Professional leaders had a masters-/ doctoral-level training in psychology or social work. Peers were PLWH ex-smokers recruited from the clinic. Tailored: its content addressed numerous concerns of particular relevance to PLWH smokers (e.g. specific risks of smoking to PLWH, comorbid psychiatric illness and substance use, social isolation, stress reduction, etc.) **Control:** enhanced standard of care; standardised brief (< 5 min) advice to quit cigarette smoking according to the Tobacco Dependence Treatment Handbook and a PSF self-help brochure
Outcomes	7-day PPA answering 'No' to "Have you smoked cigarettes (even a puff) in the last 7 days, including today?". Measured at days 28, 120 and 210 Validation: eCO level of, 10 ppm (Bedfont piCO+ Smokerlyzer; Bedfont Scientific Ltd., Kent, UK)
Notes	Funding: "supported by award 1R01DA036445 (JS) from the National Institutes of Health (NIH)/National Institutes on Drug Abuse (NIDA) and by the Einstein-Rockefeller-CUNY Center for AIDS Research (P30-AI124414), which is supported by the following NIH cofunding and participating institutes and centers: NIAID, NCI, NICHD, NHBL, NIDA, NIMH, NIA, FIC, and OAR. None of these sources were involved in the design, analysis, data interpretation, writing, or decision to publish the completed manuscript. The content is solely the responsibility of the authors and does not necessarily represent the official views of Westat or of the National Institute on Drug Abuse or the National Institutes of Health." Conflict of interest: "the authors have no funding or conflicts of interest to disclose."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised using a computer-driven randomisation algorithm that was concealed from the research assistant and the investigative team.
Allocation concealment (selection bias)	Low risk	Randomised using a computer-driven randomisation algorithm that was concealed from the research assistant and the investigative team.

Stanton 2020 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically verified
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar follow-up rates between groups > 80% and ITT
Selective reporting (reporting bias)	Low risk	None identified
Other bias	Low risk	None identified

Tindle 2022

Study characteristics	
Methods	Country: Russia Design: parallel RCT Number of centres: not specified (HIV clinical care sites) Selection: from a recently completed cohort study, as well as from HIV clinical care sites and non-clinical sites, and via snowball recruitment Definition of tobacco user/smoker: self-report smoking a mean number of ≥ 5 cpd
Participants	Number: 400 Average age: 39 years Gender: 65.7% male Sexuality: not reported Race/ethnicity: not reported Average cpd: 21 Nicotine dependence: not reported
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **All participants received:** brief guideline-based counseling on alcohol and smoking **Interventions/controls** • Arm 1: varenicline (12 weeks, standard dose, tablets) + NRT placebo (8 weeks - mouthspray) • Arm 2: NRT (8 weeks - mouthspray, 1 mg nicotine per spray) + varenicline placebo (12 weeks) • Arm 3: cytisine (25 days standard dose, tablets) + NRT placebo (8 weeks mouthspray) • Arm 4: NRT (8 weeks - mouthspray, 1 mg nicotine per spray) + cytisine placebo (25 days, tablets) **Dosage regimens** • Varenicline: 0.5 mg once daily on days 1-3 and 0.5 mg twice daily on days 4-7; then 1 mg twice daily for a total of 12 weeks • NRT: participants were instructed to use 8 sprays/d as a minimum for the first 4 weeks and to use the spray as needed during weeks 5 through 8 up to the maximum recommended daily sprays to control cravings. • Cytisine: dosing followed the traditional 25-day downward titration schedule of 1.5 mg tablets: 6 tablets/d (days 1-3), 5 tablets/d (days 4-12), 4 tablets/d (days 13-16), 3 tablets/d (days 17-20), and 1 to2 tablets/d (days 21-25)
Outcomes	Abstinence: 7-day PPA at 6 and 12 months post-intervention Validation: eCO < 10 ppm

Tindle 2022 *(Continued)*

Notes	"We did not use data from this study to compare varenicline with cytisine because placebos were only integrated for comparisons of varenicline or cytisine vs NRT." Funding: "this work was supported by grants U01AA020780, U24AA020779, and U24AA020778 from the National Institute on Alcohol Abuse and Alcoholism in support of the Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS (URBAN ARCH), P30AI042853 from the Providence/Boston Center for AIDS Research, and P30AI110527 from the Tennessee Center for AIDS Research. Dr Bryant served as scientific collaborator for the National Institutes of Health for this research activity, funded under a cooperative agreement mechanism, an approved relationship to guide scientific research as an area expert in the interest of the government and to make substantial scientific contributions through collaboration and publication of results." Conflict of interest: "Drs Tindle, Freiberg, Cheng, Gnatienko, Hahn, So-Armah, and Krupitsky reported receiving grants from the National Institutes of Health during the conduct of the study. Dr Tindle reported volunteering scientific input on the early stages of design of a phase 3 trial conducted in the US testing cytisine for smoking cessation and serving as the principal investigator for smoking cessation trials for which medications were donated by the manufacturer. Dr Cheng reported receiving personal fees from Janssen outside the submitted work. Dr Hahn reported receiving personal fees from Pear Therapeutics outside the submitted work. No other disclosures were reported."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The software package SAS was used to generate randomisation lists to assign participants as they were enrolled into the study.
Allocation concealment (selection bias)	Low risk	Study participants, investigators, staff, and physicians administering the medications were unaware to which of the 4 arms a participant was assigned.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Placebo controlled. "Study participants and staff were blinded to randomization assignment of participants."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Abstinence biochemically validated
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition rates differ significantly, with NRT arms experiencing higher rates of dropout.
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported in results paper
Other bias	Low risk	None identified

Vidrine 2012

Study characteristics

Methods	Country: USA Design: parallel RCT Number of centres: 1 health centre Selection: patients screened at clinic appointments and invited if eligible, willingness to set a quit date within 1 week was required for inclusion

Vidrine 2012 *(Continued)*

	Definition of tobacco user/smoker: self-report ≥ 5 cpd and eCO > 7 ppm
Participants	Number: 474 Average age: 45 years Gender: 70% male Sexuality: not directly reported, HIV risk group was 'men who have sex with men' for 46% and 'heterosexual contact' for 25% Race/ethnicity: 77% black Average cpd: 19.2 Nicotine dependence: mean FTND score 5.73 in intervention group, 5.82 in control group
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **Intervention:** 11 counselling sessions, based on CBT, delivered via cell phone, over 3 months. Plus access to a hotline and self-help written materials. Instructions to obtain NRT patches, details of dose, frequency and duration not described. All intervention participants also received the control interventions **Control:** 1 brief counselling session delivered face-to-face and self-help written materials. NRT as per intervention Provider: "counsellors were trained and supervised by a licensed clinical psychologist" Tailoring: intervention was tailored to PLWH through reinforcing the HIV-specific benefits of abstinence. Control was not tailored
Outcomes	Abstinence: 7-day PPA and continuous abstinence at 3, 6, and 12 months post-enrolment Validation: eCO < 7 ppm
Notes	Only PPA outcomes were included in the published report, continuous abstinence outcomes were obtained via email communication with the study authors Funding: "this work was support by a National Cancer Institute grant, R01CA097893, awarded to Dr. ERG." Conflict of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"...participants were randomized to 1 of 2 treatment groups"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome was assessed by self-report using a computer and eCO
Incomplete outcome data (attrition bias) All outcomes	Low risk	The distribution of missing participants was balanced between groups (retention was 75.8% for the intervention group, and 78.2% for the control group). Missing data imputed as missing = smoking
Selective reporting (reporting bias)	Low risk	The study was registered on clinicaltrials.gov NCT00502827, all primary outcomes were reported in full
Other bias	Low risk	None identified

Wewers 2000

Study characteristics	
Methods	Country: USA Design: parallel "quasi-experimental" controlled trial, pilot study Number of centres: 1 infectious disease clinic Selection: the study was advertised to clinic patients, interest in quitting smoking was required for inclusion Definition of tobacco user/smoker: self report ≥ 10 cpd, for ≥ 1 year
Participants	Number: 15 Average age: 40 years in intervention group, 37 years in control Gender: 100% male Sexuality: not reported Race/ethnicity: not reported Average cpd: 27 in intervention group, 28 in control Nicotine dependence: mean FTND score 4.07 in intervention group, 4.39 in control group
Interventions	Type of interventions: individual-/group-level interventions delivered directly to PLWH who smoke **Intervention:** 3 face-to-face individual counselling sessions (duration 30 min) and weekly phone calls (duration 10-15 min) over 8 weeks. Additional calls as required and written materials. NRT patches 21 mg for 6 weeks **Control:** written materials and a letter with a strong quit smoking message Provider: peer educator (PLWH ex-smoker) with a nurse as case manager. Peer was "trained by a nurse in smoking cessation treatment" Tailoring: the intervention was tailored through use of a HIV-positive peer educator, control was not tailored
Outcomes	Abstinence: PPA and continuous abstinence at 8 weeks and 8 months post-enrolment Validation: eCO < 8 ppm
Notes	Pilot study. Poor retention of control participants, retention rate at 8 months was 43% in control group and 88% in intervention group Funding: National Institutes of Health, National Institute of Allergy and Infectious Diseases, Adult AIDS Clinical Trials Group Conflicts of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"randomly assigned" but sequence generation not further described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biochemically verified
Incomplete outcome data (attrition bias) All outcomes	Low risk	The distribution of missing participants was unbalanced between groups, with high loss to follow-up in the control group at 8 months. However, since no con-

Wewers 2000 *(Continued)*

		trol participants reported abstinence at 8 weeks, this would not have effected the outcome.
Selective reporting (reporting bias)	Low risk	No study protocol was published. But all primary outcomes were reported in full
Other bias	Low risk	None identified

CBT: cognitive behavioural therapy; **CO:** carbon monoxide; **cpd:** cigarettes per day; **eCO:** expired carbon monoxide; **FDA:** US Food and Drug Administration; **FTND:** Fagerström Test for Nicotine Dependence; **HSI:** Heavy Smoking Index; **ITT**: intention-to-treat; **MI:** motivational interviewing; **NRT:** nicotine replacement therapy; **PHS:** Public Health Service (USA); **PPA:** point prevalence smoking abstinence; **ppm:** parts per million; **PLWH:** people living with HIV; **RCT:** randomised controlled trial; **SD:** standard deviation; **TQD:** target quit date

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Ashare 2021	Ineligible patient population: included people with and without HIV
Balfour 2017	Ineligible study design
Bean 2018	Ineligible study design
Beckett 2019	Ineligible study design
Brown 2019	Ineligible study design
Bui 2020	Ineligible study design
Bui 2021	Ineligible outcome: follow-up < 6months
Burkhalter 2013	Ineligible outcome: outcomes of interest not measured
Cangialosi 2020	Ineligible study design
Chew 2014	Ineligible study design
Cropsey 2013	Ineligible outcomes: follow-up < 6months
Cropsey 2015	Ineligible outcome: follow-up < 6months
Cropsey 2020	Ineligible study design
Cui 2012	Ineligible study design
Drach 2010	Ineligible study design
Elzi 2006	Ineligible study design
Ferketich 2013	Ineligible study design
Golden 2006	Ineligible study design
Healey 2015	Ineligible study design

Study	Reason for exclusion
Himelhoch 2021	Ineligible study design
Ingersoll 2005	Ineligible outcome: follow-up < 6 months
Ingersoll 2009	Ineligible outcome: follow-up < 6 months
Kierstead 2021	Ineligible outcome: follow-up < 6 months
Kim 2020	Ineligible outcome: follow-up < 6 months
Kyriacou 2015	Ineligible study design
Lazev 2004	Ineligible outcome: follow-up < 6 months
Le 2015	Ineligible study design
Ledgerwood 2015	Ineligible outcome: follow-up < 6months
Manuel 2013	Ineligible outcome: follow-up < 6 months
Marhefka 2018	Ineligible study design
Matthews 2013	Ineligible study design
Moadel 2012	Ineligible outcome: follow-up < 6 months
NCT00701896	Ineligible study design
NCT00918073	Ineligible study design
NCT01363245	Ineligible patient population
NCT02190643	Ineligible outcome: follow-up < 6 months
NCT02302859	Ineligible study design
NCT02600273	Ineligible outcomes: outcomes of interest not measured
NCT02840513	Trial withdrawn
NCT03082482	Ineligible outcome: follow-up < 6 months
NCT03580460	Ineligible outcomes: outcomes of interest not mesured
NCT03999411	Ineligible outcome: follow-up < 6 months
NCT04191278	Ineligible outcome: follow-up < 6 months
NCT04566159	Ineligible outcomes: outcomes of interest not measured
NCT04609514	Ineligible outcome: follow-up < 6 months
NCT04936594	Ineligible outcomes: outcomes of interest not measured
NCT05295953	Ineligible outcomes: outcomes of interest not measured

Study	Reason for exclusion
Orr 2018	Ineligible patient population
Pacek 2017	Ineligible outcomes: outcomes of interest not measured
Parienti 2017	Ineligible study design
Ramesh Kumar 2017	Ineligible outcome: follow-up < 6 months
Ronquillo 2016	Ineligible study design
Satterfield 2017	Ineligible patient population
Shuter 2014	Ineligible outcome: follow-up < 6 months
Shuter 2020	Ineligible outcome: follow-up < 6 months
Tornero 2009	Ineligible study design
Tsima 2020	Ineligible study design
Tucker 2017	Ineligible outcome: follow-up < 6 months
Vidrine 2006	Ineligible outcome: follow-up < 6 months
Vijayaraghavan 2017	Ineligible study design
Voggensperger 2003	Ineligible study design
Yadegarynia 2017	Ineligible study design
Zwiebel 2008	Ineligible study design: observational service review

Characteristics of studies awaiting classification *[ordered by study ID]*

Warner 2020

Methods	Country: not reported Design: parallel, single-blind 2-group RCT Number of centres: not reported Selection: not reported Definition of tobacco user/smoker: not reported
Participants	272 participants
Interventions	The trial provides personalised, evidence-based, incentivised onsite tobacco cessation to patients at their home clinic for HIV dental and medical care
Outcomes	3- and 6-month continine-/anabasine-verified abstinence
Notes	The study details are only available as an abstract.

RCT: randomised controlled trial

Characteristics of ongoing studies *[ordered by study ID]*

Cioe 2021

Study name	Peer navigation for smoking cessation in smokers with HIV
Methods	Country: USA Design: parallel, 2-group RCT Number of centres: 1 Selection: from the Miriam Hospital Immunology Center and the local community around Brown University and Providence, Rhode Island, through study fliers; as well as study adverts on social media Definition of tobacco user/smoker: smoke at least 5 cpd for > 1 year, and have a positive saliva cotinine test at baseline
Participants	Sample size: 72
Interventions	**Intervention:** peer navigation social support for smoking cessation: a 30-min session with the study nurse to discuss smoking cessation. The nurse will also discuss the importance of social support for quitting and the role of a peer navigator. Those participants who set a quit date will choose medication/s in collaboration with the nurse and/or physician. The peer navigator will be introduced and will reinforce adherence to medication. The peer navigator will ensure that the patient picks up the medication, and will help to manage side effects via physician/nurse consultation. The peer navigator will provide social support for quitting via weekly phone calls for 12 weeks. **Control:** standard care - a 30-min counseling session with a study nurse based on the 5A's. The nurse will ask about current smoking habits, advise the participant to quit, assess readiness to quit, and assist by providing resources (community programmes, quit line phone number). The nurse will calculate lung age which will serve as a motivation tool to encourage smokers to quit. Those willing to set a quit date will be instructed to call their physician for cessation medication and will provided with the National Cancer Institute self-help pamphlet. Those participants not willing to set a quit date will be instructed to contact their physician when they are ready.
Outcomes	Feasibility and acceptability: session attendance (time frame: week 24) Quit attempts: defined as a period of 24 h of no cigarette smoking (time frame: week 24) Point prevalence abstinence: biochemically verified 7-day PPA (verified by saliva cotinine radioimmune assay analysis (cut-off value of < 15 ng/mL) in those not currently using NRT or other nicotine-containing products). Breath samples for eCO will be obtained at each study visit (time frame: week 24) Treatment satisfaction (time frame: week 24)
Starting date	14 January 2020
Contact information	Dr Patricia A Cioe; Patricia_Cioe@brown.edu
Notes	Funding: "this research is receiving financial support from the National Cancer Institute, grant number 5R21CA243906, to Dr Patricia Cioe. This work is being facilitated by the Providence/Boston Center for AIDS Research (P30AI042853)." Conflict of interest: "the authors have no conflicts of interest to declare."

Côté 2015

Study name	Evaluation of a web-based tailored intervention (TAVIE en santé) to support people living with HIV in the adoption of health promoting behaviours

Côté 2015 *(Continued)*

Methods	Country: Canada Design: parallel, 2-group RCT Number of centres: not specified Selection: in medical clinics, community agencies and community organisations working with PLWH: health professionals and stakeholders will be invited to inform their clientele about this study using traditional methods, such as posters and information brochures. Definition of tobacco user/smoker: not specified
Participants	Sample size: 750
Interventions	**Intervention:** Website A: patients assigned to this arm will be invited to consult a web-based tailored intervention called TAVIE en santé (TAVIE: Traitement, Assistance Virtuelle Infirmière et Enseignement). TAVIE en santé is a web-based tailored multicomponent intervention addressing smoking cessation, physical activity and healthy eating. Each component consists of 7 interactive computer sessions lasting 5-10 min. The sessions, hosted by a virtual nurse, aim to develop and strengthen skills required for behaviour change. **Control:** Website B: patients assigned to this arm will be invited to consult a validated list of 5 predetermined websites offering information about the health behaviour they chose: being physically active, following a healthy diet or quitting smoking. These websites offers reliable information and their content were validated by experts.
Outcomes	Change in tobacco smoking: measured with a single question, "In the past 7 days, have you had a smoke or even just a single puff? (0 = no/1 =y es)" (time frame: 6 months)
Starting date	December 2015
Contact information	
Notes	Funding: "this study was funded by the Funded by Canadian Institutes of Health Research (CIHR). This study is supported by the CIHR Canadian HIV Trials Network (CTN 288)." Conflict of interest: "the authors declare that they have no competing interests."

Edelman 2021

Study name	A SMARTTT approach to treating tobacco use disorder in persons with HIV (SMARTTT)
Methods	Country: USA Design: parallel, 2-group RCT (at first stage) Number of centres: 3 Selection: from the participating centres using proactive screening via electronic medical review of patients scheduled for routine clinical visits, self-referral via recruitment flyers, and clinician referral Definition of tobacco user/smoker: have smoked ≥ 100 cigarettes over their lifetime, smoke cigarettes every day or some days, and smoke on average ≥ 5 cpd
Participants	Sample size: 632
Interventions	At first stage, participants are randomised to either NRT alone, or NRT plus contingency management (CM; financial reward for abstinence from tobacco). At the second stage, participants will be futher allocated into groups depending on whether they have responded or not to their assigned treatment, creating 6 groups. Group 1 (12 weeks NRT + CM/12 weeks NRT + CM): NRT combined with CM (financial reward for abstinence from tobacco). Responders remain on same treatment for second 12 weeks.

Edelman 2021 *(Continued)*

	Group 2 (12 weeks NRT + CM/12 weeks varenicline or bupropion + CM): NRT combined with CM. Non-responders switch to varenicline or bupropion combined with CM for second 12 weeks. Group 3 (12 weeks NRT + CM/12 weeks NRT + CM plus): NRT combined with CM. Non-responders switch to NRT combined with intensified CM for second 12 weeks. Group 4 (12 weeks NRT/12 weeks NRT): NRT alone. Responders remain on NRT. Group 5 (12 weeks NRT/12 weeks varenicline or bupropion): NRT alone. Non-responders switch to varenicline or bupropion alone for second 12 weeks. Group 6 (12 weeks NRT/12 weeks NRT + CM): NRT alone. Non-responders switch to NRT combined with CM for second 12 weeks.
Outcomes	• eCO confirmed abstinence at 24 weeks: abstinence from tobacco confirmed by eCO (time frame: 24 weeks from baseline) • VACS Index 2.0: a validated measure of morbidity and mortality (time frame: 24 weeks from baseline) • CD4 count: median CD4 count adjusting for baseline (time frame: 24 weeks from baseline) • HIV viral load: the proportion of participants with HIV viral load suppression (time frame: 24 weeks from baseline) • Identification of barriers and facilitators to delivering our intervention to inform future implementation (time frame: baseline and up to 4 years)
Starting date	27 July 2020
Contact information	EJ Edelman: ejennifer.edelman@yale.edu
Notes	Funding: "this work is funded by the National Cancer Institute (R01CA243910). KB received funding from the National Institute of Drug Abuse (K12DA000167) during the conduct of this work." Conflict of Interest: "the authors have no conflicts of interest to disclose."

Garey 2021

Study name	Evaluation of an integrated treatment to address smoking cessation and anxiety/depressive symptoms among people living with HIV
Methods	Country: USA Design: parallel, 3-group RCT Number of centres: 3 Selection: participants will be recruited via referrals from doctors within the infectious disease units at the study sites (2 of the project co-investigators, Drs Robbins and Giordano, are healthcare providers who specialise in HIV, and will aid in recruiting participants), posted fliers at community organisations, and through multimedia platforms, such as LGBTQ dating sites, Craigslist, and healthcare system research portals Definition of tobacco user/smoker: smokes an average of at least 5 cigarettes in the past week or weekend
Participants	180 participants
Interventions	**Intervention:** smoking cessation treatment involving an integrated CBT-based, transdiagnostic approach to treat anxiety, depression, and nicotine dependence concurrently (QUIT). Consists of 9 x 60-min treatment sessions: 5 pre-quit sessions and 4 post-quit sessions with quit occurring at session 7. A total intervention period of 10 weeks (including the pre-randomisation treatment session 1)

Garey 2021 *(Continued)*

	Control: standard smoking treatment (time-matched control): consists of 9 x 60-min treatment sessions: 5 pre-quit sessions and 4 post-quit sessions with quit occurring at session 7. A total intervention period of 10 weeks (including the pre-randomisation treatment session 1) Smoking status assessment (standard care): standard care will consist of 9 assessment-only appointments.
Outcomes	• Self-reported 7-day PPA will be assessed at each session, and at 1-month, 3-month, and 6-month follow-up (i.e. post-quit) verified via an eCO breath analysis at all time points, as well as biochemically confirmed by saliva cotinine for participants who do not report NRT use and a urine assessment of anabasine for participants who report using NRT. • Anxiety and depressive symptoms • Transdiagnostic mechanisms • Cost-effectiveness
Starting date	December 2019
Contact information	Dr Conall O'Cleirigh; cocleirigh@mgh.harvard.edu
Notes	Funding: "the study is funded by the National Institute on Drug Abuse (NIDA; R01DA047933)." Conflict of interest: information not reported

Marhefka 2021

Study name	A tailored telehealth group tobacco cessation treatment program for people with HIV
Methods	Country: USA Design: parallel, 2-arm, attention-matched control, RCT Number of centres: not applicable (video conferencing interventions) Selection: through HIV care providers (particularly those employed by the Ryan White HIV/AIDS Program), web-based targeted advertising and posts on social networking sites, incentivised peer referral, advertisement at conferences, and HIV/AIDS or pride events Definition of tobacco user/smoker: self-report of smoking > 1 cpd and positive cotinine test
Participants	482 participants
Interventions	**Intervention:** Positively Smoke-Free Video-Group: all participants will receive standard, 5-min brief cessation counseling and the offer of NRT over video-conferencing with a study staff member. Those accepting will be assisted in obtaining a 3-month supply of NRT patches (dose appropriate to daily cigarette intake) and advised to begin using them on quit day. In addition, they receive an 8-session social cognitive theory-based, facilitator and peer-led group intervention delivered by video group conference and designed to help encourage tobacco smoking cessation specifically among PLWH. Content focuses on providing information, increasing motivation to quit, and increasing self-efficacy to resist smoking temptations. After session 8, four booster sessions will provide opportunities to review skills and problem solve. **Control:** Healthy Relationships/Healthy Living-Video Group: all participants will receive standard, 5-minute brief cessation counseling and the offer of NRT over video-conferencing with a study staff member. Those accepting will be assisted in obtaining a 3-month supply of NRT patches (dose appropriate to daily cigarette intake) and advised to begin using them on quit day. In addition, they receive an 8-session adapted version of an evidence-based programme noted in the CDC compendium for effective HIV interventions delivered via video group format. The intervention sessions illustrate realistic scenarios related to possible HIV disclosure and sexual possibility situations that then provide a springboard for problem-solving and discussion. Additional sessions 9–12 expand on content discussed in earlier sessions.

Marhefka 2021 *(Continued)*

Outcomes	• 7-day PPA at 360 days with biochemical confirmation • Biochemically confirmed 30-day PPA at day 360 • Biochemically confirmed sustained abstinence at day 360 • Biochemically confirmed 7-day PPA at days 42, 90, and 180 • Biochemically confirmed 30-day PPA at days 90 and 180 • Biochemically confirmed sustained abstinence at day 180 • Self-efficacy for abstinence at days 42 and 90
Starting date	Not specified
Contact information	Stephanie Marhefka; smarhefk@usf.edu
Notes	Funding: "this work was supported by the National Institutes of Health, National Cancer Institute [R01CA243800]." Conflict of Interest: "the authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper."

McClure 2021

Study name	Improving the reach & effectiveness of smoking cessation services targeted to veterans living with HIV (WISH)
Methods	Country: USA Design: parallel, 2 group RCT Number of centres: not applicable (participants recruited from US mainland) Selection: identified through the VA Corporate Data Warehouse (CDW) Definition of tobacco user/smoker: currently smoking ≥ 5 cpd
Participants	500 participants
Interventions	**Intervention:** Wellness Intervention for Smokers with HIV (WISH): mobile phone (voice and text message) delivered intervention that addresses both smoking and a number of other personally relevant health behaviours (such as treatment engagement, medication adherence, stress and mood management, social support, alcohol use, etc.). For those not yet ready to quit, WISH is designed to build and strengthen motivation and self-confidence for quitting, while smokers also work on other personal health goals. Once ready to quit smoking, participants receive evidence-based cognitive-behavioral counseling and encouragement to access NRT or other appropriate pharmacotherapy through usual care VA procedures. Medications will not be prescribed or dispensed by the study. **Control:** standard care - referral to standard evidence-based cessation services available nationally to Veterans, including the National VA Quitline and SmokefreeVET texting programme
Outcomes	• 7-day PPA: by self-report and biochemically confirmed via saliva cotinine for a small selected group of individuals. Cotinine levels < 10 ng/mL and a self-report of 7-day PPA will be required to be coded a nonsmoker (time frame: 6 months post-randomisation) • Any 24-h intentional quit attempt: presence of an intentional quit attempt (yes/no) reported between randomisation and 6-month follow-up. Quit attempts will be assessed at each follow-up (time frame: 3 and 6 months post-randomisation) • Floating prolonged abstinence: the start point floats based on one's actual quit date rather than a pre-determined quit date (time frame: 3 and 6 months post-randomisation) • 7-day self-report PPA: self-report of abstinence from smoking, even a puff (time frame: 3 and 6 months post-randomisation)

McClure 2021 *(Continued)*

	• 30-day self-report PPA: self-report of abstinence from smoking, even a puff (time frame: 3, 6, 12 months post-randomisation) • Cigarettes smoked per day: self-report; even a puff counts as smoking (time frame: 3 and 6 months post-randomisation) • HIV-specific smoking knowledge (time frame: 3 and 6 months post-randomisation) • Motivation to quit smoking (time frame: 3 and 6 months post-randomisation) • Smoking cessation related to self-efficacy (time frame: 3 and 6 months post-randomisation) • Nicotine withdrawal symptom management (behavioural skills) (time frame: 3 and 6 months post-randomisation) • Cessation medication use and adherence (behavioural skills): self-report and health records (pharmacy) monitoring (time frame: 3 and 6 months post-randomisation) • Absolute CD4 count (time frame: 6 and 12 months post-randomisation) • VACS Index 2.0 (time frame: 6 and 12 months post-randomisation) • Intentional quit attempt frequency and duration (time frame: 3 and 6 months post-randomisation)
Starting date	4 June 2021
Contact information	Jennifer McClure; Jennifer.B.McClure@kp.org
Notes	Funding: "this research is supported by the National Cancer Institute (NCI; R01CA249307)." Conflict of Interest: "the authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper."

McKetchnie 2021

Study name	Effectiveness of a smoking cessation algorithm integrated into HIV primary care
Methods	Country: USA Design: parallel, 2-arm RCT Number of centres: 3 Selection: recruited from the CFAR CNICS if they endorse smoking cigarettes on their CNICS clinical assessment Definition of tobacco nuser/smoker: smoking ≥ 5 cpd for the past month
Participants	600 participants
Interventions	Algorithm treatment: the algorithm is structured so that participants who report current motivation to quit smoking are prescribed varenicline, bupropion, or a combination of bupropion and NRT. Those who do not report current motivation to quit smoking are still recommended NRT, with dosing based on past quit attempts and current smoking habits. All participants will receive a brief handout on behavioral strategies and tips for smoking cessation, and will also be referred to the national quit line. Enhanced treatment as usual: all participants will receive a brief handout on behavioral strategies and tips for smoking cessation, and will also be referred to the national quit line. Independent of the study, a medical provider may elect to prescribe smoking cessation pharmacotherapy as part of standard care.
Outcomes	• The proportion of participants with 7-day PPA at 6 months • 24-h quit attempt – dichotomised yes/no – at 6 months • For cigarette reduction: change in cpd at baseline and 6-month follow-up • Difference in provider behaviour (e.g. tobacco screening, number of prescriptions written) baseline to those at 6-month follow-up

McKetchnie 2021 *(Continued)*

	• Difference in provider attitudes toward providing smoking cessation treatment at baseline to those at 6-month follow-up • Cost-effectiveness analysis will examine the incremental cost per quit, taking the provider organisation's perspective over the 6-month study period
Starting date	Not provided
Contact information	Samantha M McKetchnie; Smarquez1@mgh.harvard.edu
Notes	Funding: "funding for this project came from the National Institute on Drug Abuse R01DA044112." Conflict of Interest: "the authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper."

NCT01800019

Study name	The Canadian HIV quit smoking trial: tackling the co-morbidities of depression and cardiovascular disease in HIV + smokers (CANQUIT)
Methods	Country: Canada Design: randomised 2x2 factorial assignment Number of centres: 1 Selection: information not provided Definition of tobacco user/smoker: current smoker (> 5 cpd)
Participants	256 participants
Interventions	NRT arm: transdermal patch (7 mg-42 mg depending on cpd at study baseline, and withdrawal symptoms) for up to 24 weeks. Additionally, participants provided with a supply of short-acting nicotine gum in order to supplement their long-acting NRT patch regimen. Individuals who smoke their first cigarette more than 30 min after waking are advised to use the 2 mg NRT gum. Participants who smoke their first cigarette within 30 min of waking will be advised to use the 4 mg NRT gum. Both NRT gum dosages will be recommended for use on an ad lib basis to address cravings and/or withdrawal symptoms, up to a maximum of 12 pieces of NRT gum per day. NRT and HIV-tailored quit-smoking counseling arm: NRT as in the NRT arm plus HIV-tailored smoking cessation counseling consisting of face-to-face sessions with a trained smoking cessation counselor at the start of the study, on chosen quit date, and then at weeks 4, 8, 12 and 24; supportive telephone calls if needed. Varenicline (VR) arm: varenicline 0.5 mg once daily for 3 days (i.e. day 1-3 of the week prior to quit date) 0.5 mg twice daily for 4 days i.e. day 4-7) and 1 mg twice daily for the remainder of the treatment period. For 24 weeks (+ 1 week of dose escalation, total of 25 weeks) Varenicline (VR) and HIV-tailored quit-smoking counseling: varenicline as in the VR arm plus HIV-tailored smoking cessation counseling consisting of face-to-face sessions with a trained smoking cessation counselor at the start of the study, on chosen quit date, and then at weeks 4, 8, 12 and 24; supportive telephone calls if needed.
Outcomes	• 7-day self-reported abstinence, and 4-week continuous abstinence rates at week 48, confirmed by expired CO levels measured using a piCO+ Smokerlyzer (smoke-free defined as eCO < 10 ppm) • Smoking cessation treatment integrity and patient satisfaction (time frame: baseline through week 48) • Behavioural-psychosocial measures (time frame: baseline to week 48) • Cardiovascular parameters (time frame: from baseline through 48 weeks) • Immune function (time frame: 12, 24, and 48 weeks)

NCT01800019 *(Continued)*

Starting date	January 2014
Contact information	Information not provided
Notes	Funding: not provided Conflict of interest: information not provided

NCT01886924

Study name	Computer MI for tobacco quitline engagement in smokers living with HIV (MI-HIV)
Methods	Country: USA Design: parallel 2-group RCT Number of centres: 1 Selection: information not provided Definition of tobacco user/smoker: current smoker (i.e. at least 10 cpd)
Participants	100 participants
Interventions	Brief computer MI intervention to motivate tobacco quitline use Computer-delivered nutrition education control condition
Outcomes	Engaged in tobacco cessation treatment since end of treatment intervention (time frame: 6 months) Number of quit attempts since last assessment (time frame: 6 months) Point prevalence smoking abstinence - last 7 days from time of assessment (time frame: 6 months)
Starting date	February 2014
Contact information	Not provided
Notes	Funder: not provided Conflict of interest: information not provided

NCT01965405

Study name	Smoking cessation for people living with HIV/AIDS
Methods	Country: USA Design: parallel RCT Number of centres: 1 Selection: information not provided Definition of tobacco user/smoker: smoke > 10 cpd
Participants	165 participants
Interventions	Phase 1 • Brief counselling plus bupropion

NCT01965405 *(Continued)*

	• Brief counseling, bupropion, and brief high-magnitude prize contingency management (i.e. participants have the chance to win incentives (prizes) when they provide biological test results (eCO and cotinine) that are negative for recent smoking) Phase 2a (non-responders) • Bupropion, continued counseling, monitored support to quit smoking (i.e. brief supportive sessions and monitoring of smoking cessation efforts) • Bupropion, monitored support to quit smoking, prize contingency management for abstinence Phase 2b (responders) • Bupropion, no additional treatment • Bupropion, continued monitoring and low-intensity prize contingency management
Outcomes	• Urinary cotinine (time frame: change from baseline: weekly in treatment phase 1; between 0-16 times during treatment phase 2 (non-responders meet 16 times; responders meet 0 or 6 times depending on group); follow-up interviews (post-phase 1, post-phase 2, 6-months and 12-months)) • Longest duration of continuous abstinence (time frame: change from baseline: weekly through treatment phase 1; between 0-16 times during treatment phase 2 (non-responders meet 16 times; responders meet 0 or 6 times depending on group)) • 7-day point-prevalence (time frame: follow-up interviews: post-phase 1, post-phase 2, 6-months and 12-months after treatment initiation) • CO results (time frame: change from baseline: weekly in treatment phase 1; between 0-16 times during treatment phase 2 (non-responders meet 16 times; responders meet 0 or 6 times depending on group); follow-up interviews (post-phase 1, post-phase 2, 6-months and 12-months))
Starting date	August 2013
Contact information	Not provided
Notes	Funding: not provided Conflict of interest: information not provided

NCT02460900

Study name	Optimizing smoking cessation for people with HIV/AIDS who smoke
Methods	Country: USA Design: randomised, 2x2 factorial design, double-blind (placebo control for the pharmacotherapy) Number of centres: 1 Selection: information not provided Definition of tobacco user/smoker: currently self-report smoking ≥ 10 cpd or a score of > 5 of eCO as measured by Covita micro smokrlyzer
Participants	184 participants
Interventions	Varenicline and standard care: participants will receive varenicline and standard care Placebo and standard care: participants will receive placebo and standard care Positively Smoke Free and placebo: participant will receive Positively Smoke Free (a tailored behavioural intervention delivered over 8 weeks) and placebo Positively Smoke Free and varenicline: participant will receive Positively Smoke Free and varenicline

NCT02460900 *(Continued)*

Outcomes	• Number of participants with 7-day PPA at 36 weeks: 7-day PPA based on self-reported tobacco use (not even a puff) during the 7 days preceding the assessment and a CO ≤ 10 ppm as measured by Covita micro smokrlyzer at week 36 (time frame: 36 weeks) • Biomarker evaluation: effect of smoking abstinence on levels of cardiac specific biomarkers (time frame: 36 weeks)
Starting date	July 2016
Contact information	Not provided
Notes	Funding: not provided Conflict of interest: information not provided

NCT02982772

Study name	Patch study - intervention for HIV positive smokers
Methods	Country: USA Design: randomised, 2-group parallel design Number of centres: 1 Selection: information not provided Definition of tobacco user/smoker: smokers eligible regardless of cpd
Participants	600 participants
Interventions	Combination of brief behavioural intervention plus NRT. The test product is a transdermal nicotine patch and nicotine replacement gums for 12 weeks. The dosage of the test product depends on the new algorithm (amount, addiction, prior attempts). Doses will be tailored and adjusted as needed. Brief behavioural intervention plus NRT. The test product is a transdermal nicotine patch plus regular flavoured gums for 10 weeks. The dosage of the test product follows the product guidelines and depends on the amount of cigarettes used.
Outcomes	Rates of smoking cessation: verified continuous abstinence (carbon monoxide < 10 ppm and cotinine < 15 ng/mL) (tme frame: 3, 6 and 12 months) Change in clinical outcomes (time frame: 6 and 12 months) • CD4 (counts and percentage) • HIV viral load (logs) • Vital signs (blood pressure in mm Hg, breaths per minute, beats per minute) • Anthropometric measures (body mass index = weight (kilograms)/height(meters^2), waist and hip circumference in inches) • In health-related quality of life measured as changes in the total score of health-related quality of life survey • Scale title: smoking cessation quality of life (SCQoL) - physical subscale minimum 9, maximum 27 (higher scores = worse outcome) Prevalence of side effects - safety (time frame: baseline - 6 and 12 months)
Starting date	May 2016
Contact information	Not provided
Notes	Funding: not provided

NCT02982772 *(Continued)*

	Conflict of interest: information not provided

NCT03342027

Study name	Smoking cessation interventions for people living with HIV in Nairobi, Kenya
Methods	Country: Kenya Design: randomised, 4-groups factorial design, double-blind (placebo control for the pharmacotherapy) Number of centres: 1 Selection: information not provided Definition of tobacco user/smoker: scores > 7 ppm of eCO on the Smokelyzer; and currently self-report smoking approximately 5 cpd
Participants	300 participants
Interventions	Bupropion + Positively Smoke Free (an 8-session, tailored behavioral treatment for smoking cessation) Bupropion + standard care (brief advice to quit provided in a standardised format bupropion) Placebo (matched to bupropion) + Positively Smoke Free Placebo + standard care
Outcomes	7-day abstinence: defined as self-reported no smoking in the past 7 days + CO < 7 ppm (time frame: 36 months)
Starting date	1 August 2020
Contact information	Wendy Potts MS, + 1 (410) 706-2490; wpotts@som.umaryland.edu Patience Oduor, + 254 (0) 780445855 POduor@mgic.umaryland.edu
Notes	Funding: not provided Conflict of interest: information not provided

NCT03670316

Study name	Effectiveness of a smoking cessation algorithm integrated into HIV primary care
Methods	Country: USA Design: randomised, 2-group, parallel design Number of centres: not reported Selection: information not provided Definition of tobacco user/smoker: smoking ≥ 5 cpd for the past month
Participants	600 participants
Interventions	Experimental: algorithm treatment plus referral to quitline - will be assigned a pharmacotherapy treatment regimen recommended to their provider Active comparator: quitline - will be referred to quitlines, telephone-based tobacco cessation services

NCT03670316 *(Continued)*

Outcomes	• 7-day PPA at 6 months • cpd at 6 months • 24-h quit attempts at 6 months • Number of prescriptions written at 6 months
Starting date	17 August 2020
Contact information	Mariel Parman; marielparman@uabmc.edu
Notes	Funding: not provided Conflict of interest: information not provided

NCT04176172

Study name	Optimizing tobacco use treatment for PLWHA
Methods	Country: USA Design: randomised, 2-group, parallel design Number of centres: not provided Selection: information not provided Definition of tobacco user/smoker: smoke daily for the past 30 days
Participants	340 participants
Interventions	Experimental: varenicline or nicotine patch plus standard behavioural smoking cessation treatment with Managed Problem Solving adherence intervention Active comparator: varenicline and standard cessation counseling
Outcomes	• PPA (time frame: 26 weeks (24 weeks post-TQD)) • 6-month quit rate (time frame: 6 months) • Prolonged abstinence (time frame: 26 weeks (24 weeks post-TQD)) • Continuous abstinence (time frame: 26 weeks (24 weeks post-TQD)) • Time to 7-day relapse (time frame: 26 weeks (24 weeks post-TQD))
Starting date	17 February 2020
Contact information	Robert Schnoll, PhD; schnoll@pennmedicine.upenn.edu Brian Hitsman, PhD; b-hitsman@northwestern.edu
Notes	Funding: not provided Conflict of interest: information not provided

NCT04532970

Study name	BAPS in Botswana: the Thotloetso trial
Methods	Country: Botswana Design: randomised, 2-groups, parallel design Number of centres: not reported

NCT04532970 *(Continued)*	
	Selection: information not provided Definition of tobacco user/smoker: smoking cigarettes daily for the past 30 days
Participants	650 participants
Interventions	Experimental: combination of 2 different types of smoking cessation counselling Control: standard cessation counselling
Outcomes	Smoking cessation (time frame: at week 26, end of treatment)
Starting date	6 May 2021
Contact information	Robert Gross, MD; grossr@pennmedicine.upenn.edu Robert Schnoll, PhD; schnoll@pennmedicine.upenn.edu
Notes	Funding: not provided Conflict of interest: information not provided

NCT04725617	
Study name	Wellness intervention for smoking and HIV (WISH)
Methods	Country: USA Design: randomised, 2-groups, parallel design Number of centres: not reported Selection: Information not provided Definition of tobacco user/smoker: smoke at least 5 cpd
Participants	200 participants
Interventions	Approach 1: a behavioural health intervention administered by a clinical psychologist, in addition to administration of medication (varenicline), and counseling, during 6 study visits Approach 2: unclear
Outcomes	• Change in smoking cessation (time frame: change in smoking cessation from baseline to end of 13-week timeline and 6 month follow-up) • Change in sleep duration (time frame: change in sleep duration from baseline to end of 13-week timeline and 6-month follow-up)
Starting date	February 2021
Contact information	Manuel Acuna; macuna@psychiatry.arizona.edu Ryan Weltzer, MS; ryanweltzer@arizona.edu
Notes	Funding: not provided Conflict of interest: information not provided

NCT04808609

Study name	Smoking cessation pilot for people living with HIV
Methods	Country: USA Design: randomised, 2-groups, parallel design Number of centres: not reported Selection: information not provided Definition of tobacco user/smoker: ≥ 6 CO into a breath analyser at baseline; and smokes ≥ 5 cpd for the past 30 days
Participants	40 participants
Interventions	Intervention group: receives standard smoking cessation counseling and NRT plus access to the Lumme app that tracks smoking behaviours and provides cessation support Control group: receives standard smoking cessation counseling and NRT
Outcomes	Percentage of participants with biochemically verified 7-day point prevalence smoking/tobacco abstinence (time frame: baseline, 12 weeks follow-up)
Starting date	6 October 2020
Contact information	Rebecca Schnall, PhD, RN (Principal Investigator), Columbia University
Notes	Funding: not provided Conflict of interest: information not provided

NCT04994444

Study name	Preloading with nicotine replacement therapy in HIV-positive smokers to improve self-efficacy and quit attempts
Methods	Country: USA Design: randomised, 2-groups, parallel design Number of centres: not reported Selection: information not provided Definition of tobacco user/smoker: smoking at least 5 cpd; eCO level > 5
Participants	60 participants
Interventions	Experimental: preloading - participants will be started on nicotine patch 3 weeks prior to quit date. At quit date they will use patch and lozenge or gum for 8 weeks. Active comparator: standard treatment - participants will start combination NRT (patch/gum or patch/lozenge) on their assigned quit date. NRT will be provided for 8 weeks.
Outcomes	• Adherence to NRT (time frame: week 12) • 7 day PPA (time frame: week 16)
Starting date	1 September 2021
Contact information	Patricia A Cioe, PhD; patricia_cioe@brown.edu
Notes	Funding: not provided Conflict of interest: information not provided

NCT05019495

Study name	Optimizing tobacco treatment delivery for people living with HIV
Methods	Country: USA Design: randomised, 2-groups, parallel design Number of centres: not reported Selection: information not provided Definition of tobacco user/smoker: self-reported current smoker
Participants	231 participants
Interventions	Experimental: ProMOTE - in the PrOMOTE group, the participants will be contacted by the clinical pharmacist on the tobacco treatment staff 3 times for medication prescriptions and refills. They will also receive brief counseling and motivational interviewing by the clinical pharmacist. No intervention: treatment as usual
Outcomes	Tobacco use abstinence (time frame: 7 days)
Starting date	1 December 2021
Contact information	Madeline G Foster; fostemad@musc.edu Alana Rojewski; rojewski@musc.edu
Notes	Funding: not provided Conflict of interest: information not provided

NCT05020899

Study name	Quit For Life (QFL): smoking cessation among Chinese smokers living with HIV
Methods	Country: China Design: randomised, 2-groups, parallel design Number of centres: not reported Selection: information not provided Definition of tobacco user/smoker: smokes ≥ 5 cpd
Participants	109 participants
Interventions	Experimental: QFL Group - participants randomised to this arm will receive an 8-week quit smoking programme delivered by trained counselors and messages to their cell phones. Participants will also be offered NRT (gum or patch, depending on which one is available) and a self-help guide with information about quitting smoking. Active comparator: control group - participants randomised to this arm will be offered NRT (gum or patch, depending on which one is available) and a self-help guide with information about quitting smoking.
Outcomes	Number of participants with biochemically verified smoking cessation
Starting date	24 February 2022
Contact information	Lisa Quintiliani, PhD (Principal Investigator), Boston Medical Center

NCT05020899 *(Continued)*

	Hao Liang, PhD (Principal Investigator), Guangxi Medical University
Notes	Funding: not provided Conflict of interest: information not provided

NCT05030766

Study name	Testing integrative smoking cessation for HIV patients
Methods	Country: USA Design: randomised, 2-groups, parallel design Number of centres: not reported Selection: information not provided Definition of tobacco user/smoker: have smoked ≥ 5 cpd in the past year
Participants	100 participants
Interventions	Experimental: mindfulness training (MT) plus NRT (NRT) Group - participants who receive the MT intervention for 4 weeks in addition to 6 weeks of NRT. These participants are responders (have quit smoking at the 1-month follow-up) or non-responders (those who have not quit smoking at the 1-month follow-up) and randomised to receive no additional intervention. Experimental: contingency management (CM) plus NRT Group - participants who receive the CM intervention for 4 weeks in addition to 6 weeks of NRT. These participants are responders (have quit smoking at the 1-month follow-up) or non-responders (those who have not quit smoking at the 1-month follow-up) and randomised to receive no additional intervention. Experimental: MT plus NRT with additional CM Group - participants who received the MT intervention for 4 weeks with 6 weeks of NRT and are non-responders (those who have not quit smoking at the 1-month follow-up) and randomised to receive an additional CM intervention for another 4 weeks. Experimental: CM plus NRT with additional MT Group - participants who received the CM intervention for 4 weeks with 6 weeks of NRT and are non-responders (those who have not quit smoking at the 1-month follow-up) and randomised to receive an additional MT intervention for another 4 weeks.
Outcomes	Number of participants reporting 7-day PPA (time frame: up to 22 weeks)
Starting date	4 January 2022
Contact information	Taghrid Asfar, MD, MSPH; tasfar@med.miami.edu Laura McClure, MSPH; lmcclure@med.miami.edu
Notes	Funding: not provided Conflict of interest: information not provided

NCT05162911

Study name	Implementing tobacco use treatment in HIV clinics Vietnam (Vquit)
Methods	Country: Vietnam Design: randomised, 3-group parallel design

NCT05162911 *(Continued)*

	Number of centres: 13 outpatient clinics Selection: information not provided Definition of tobacco user/smoker: current tobacco user
Participants	672 participants
Interventions	Active Comparator: Ask, Advise, Assist (AAA) and Refer Active Comparator: AAA plus referral to onsite counselor (Counsel) Active Comparator: AAA + Counsel + N (nicotine gum)
Outcomes	• Carbon test at 6-months of smoking abstinence (time frame: 6-months smoking abstinence) • Factors that may influence tobacco cessation, and sustainability of the interventions tested (time frame: 18 months)
Starting date	23 November 2021
Contact information	Donna Shelley, MD MPH; ds186@nyu.edu Contact: Nam Nguyen, MD DrPH; ntnam@isms.org.vn
Notes	Funding: not provided Conflict of interest: information not provided

NCT05339659

Study name	Randomized pilot study of a mHealth app for ambivalent smokers living with HIV
Methods	Country: USA Design: randomised, 2-group parallel design Number of centres: not reported Selection: information not provided Definition of tobacco user/smoker: smoke cigarettes
Participants	50 participants
Interventions	mHealth app consisting of standard, best-practice information and guidance to help people stop smoking mHealth app consisting of standard, best-practice information and guidance to help people stop smoking + additional experimental content targeted to smokers living with HIV who are ambivalent about quitting smoking
Outcomes	7-day PPA
Starting date	2 June 2022
Contact information	Jennifer Director, Investigative Science; jennifer.b.mcclure@kp.org Sophia Mun; sophia.y.mun@kp.org
Notes	Funding: not provided Conflict of interest: information not provided

Vidrine 2021

Study name	Automated video-assisted smoking treatment for people living with HIV
Methods	Country: USA Design: randomised, 2-group parallel design Number of centres: not reported Selection: information not provided Definition of tobacco user/smoker: smoked ≥ 100 cigarettes in lifetime; and currently self-report smoking > 5 cpd
Participants	500 participants
Interventions	Participants randomised to standard treatment (ST) will be provided with a 10-week supply of nicotine patches and lozenges. ST participants will be connected with their state's tobacco quitline services and will complete weekly, 4-item smartphone assessments electronically for 26 weeks. The weekly assessments consist of questions on smoking status, motivation, self-efficacy, and perceived stress. Participants randomised to automated treatment (AT) will be given a 10-week supply of nicotine patches and lozenges. AT will also comprise: • 12 proactive treatment videos, delivered weekly, that are tailored on smoking status, motivation, agency, and/or negative affect/stress • 26 weeks of on-demand access to treatment content • 26 weeks of text content
Outcomes	Self-reported 7-day abstinence smoking status (time frame: 12-month follow-up)
Starting date	12 November 2021
Contact information	Sarah R Jones; Sarah.Jones@moffitt.org
Notes	Funding: "This research is supported by an award (R01CA243552, Principal Investigator DJV) from the National Institutes of Health/National Cancer Institute" Conflict of interest: none declared

5As: Ask, Advise, Assess, Assist, and Arrange; **CBT:** cognitive behavioural therapy; **CD4:** CD4 T-cells; **CDC:** Centers for Disease Control and Prevention; **CFAR CNICS:** Center for AIDS Research Network of Integrated Clinical Systems; **CO:** carbon monoxide; **cpd:** cigarettes per day; **eCO:** expired carbon monoxide; **LGBTQ:** lesbian, gay, bisexual, transgender or queer; **MI:** motivational interviewing; **NRT:** nicotine replacement therapy; **PLWH:** people living with HIV; **PrOMOTE:** Proactive Outreach with Medication Opt-out for Tobacco Treatment Engagement; **PPA:** point-prevalence abstinence; **ppm:** parts per million; **RCT:** randomised controlled trial; **TQD:** target quit date; **VACS:** Veterans Aging Cohort Study; **VA:** Veteran Administration; **WISH:** Wellness Intervention for Smokers with HIV

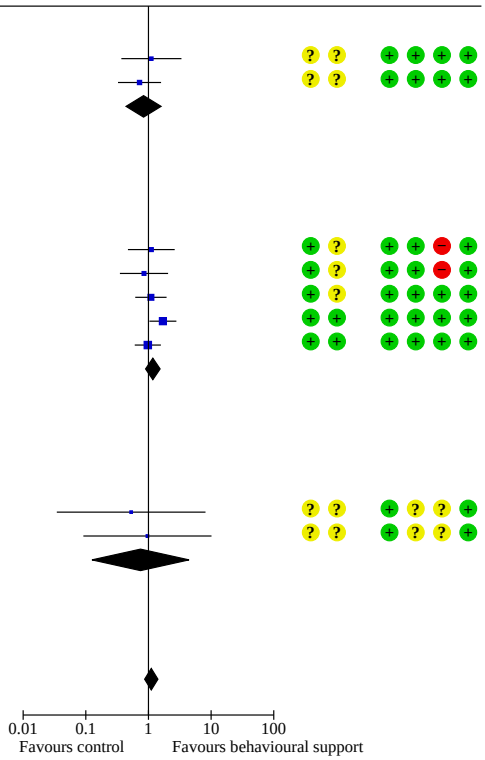
DATA AND ANALYSES

Comparison 1. Behavioural support vs brief advice or no intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Tobacco use cessation	7	2314	Risk Ratio (M-H, Random, 95% CI)	1.11 [0.87, 1.42]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1.1 Behavioural support vs brief advice	2	555	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.44, 1.59]
1.1.2 Behavioural support + NRT vs brief advice + NRT	4	1601	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.90, 1.53]
1.1.3 Behavioural support + varenicline vs varenicline	1	158	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.13, 4.44]
1.2 Quit attempts	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

Analysis 1.1. Comparison 1: Behavioural support vs brief advice or no intervention, Outcome 1: Tobacco use cessation



Study or Subgroup	Behavioural support Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
1.1.1 Behavioural support vs brief advice							
Gryaznov 2020	6	42	5	39	4.9%	1.11 [0.37 , 3.36]	? ? + + + +
Vidrine 2012	10	236	14	238	9.5%	0.72 [0.33 , 1.59]	? ? + + + +
Subtotal (95% CI)		**278**		**277**	**14.4%**	**0.84 [0.44 , 1.59]**	
Total events:	16		19				
Heterogeneity: Tau² = 0.00; Chi² = 0.40, df = 1 (P = 0.53); I² = 0%							
Test for overall effect: Z = 0.55 (P = 0.58)							
1.1.2 Behavioural support + NRT vs brief advice + NRT							
Humfleet 2013[a]	11	58	7	41	8.1%	1.11 [0.47 , 2.62]	+ ? + + − +
Humfleet 2013[b]	10	69	7	41	7.6%	0.85 [0.35 , 2.06]	+ ? + + − +
Lloyd-Richardson 2009	21	212	21	232	18.0%	1.09 [0.62 , 1.95]	+ ? + + + +
Shuter 2022	38	255	22	251	24.3%	1.70 [1.04 , 2.79]	+ + + + + +
Stanton 2020	28	216	30	226	25.8%	0.98 [0.60 , 1.58]	+ + + + + +
Subtotal (95% CI)		**810**		**791**	**83.7%**	**1.17 [0.90 , 1.53]**	
Total events:	108		87				
Heterogeneity: Tau² = 0.00; Chi² = 3.30, df = 4 (P = 0.51); I² = 0%							
Test for overall effect: Z = 1.18 (P = 0.24)							
1.1.3 Behavioural support + varenicline vs varenicline							
Shelley 2015[c]	1	51	1	27	0.8%	0.53 [0.03 , 8.14]	? ? + ? ? +
Shelley 2015[d]	2	54	1	26	1.1%	0.96 [0.09 , 10.14]	? ? + ? ? +
Subtotal (95% CI)		**105**		**53**	**1.9%**	**0.75 [0.13 , 4.44]**	
Total events:	3		2				
Heterogeneity: Tau² = 0.00; Chi² = 0.11, df = 1 (P = 0.75); I² = 0%							
Test for overall effect: Z = 0.32 (P = 0.75)							
Total (95% CI)		**1193**		**1121**	**100.0%**	**1.11 [0.87 , 1.42]**	
Total events:	127		108				
Heterogeneity: Tau² = 0.00; Chi² = 4.92, df = 8 (P = 0.77); I² = 0%							
Test for overall effect: Z = 0.83 (P = 0.41)							
Test for subgroup differences: Chi² = 1.12, df = 2 (P = 0.57), I² = 0%							

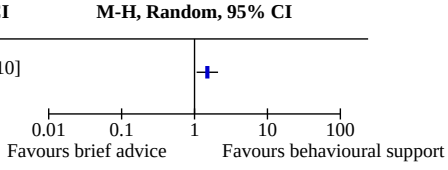
Footnotes

[a]Computer-based behavioural support + NRT vs brief advice + NRT (control arm split)
[b]Face-to-face behavioural support + NRT vs brief advice + NRT (control arm split)
[c]Varenicline + adherence-focused texts vs varenicline alone
[d]Varenicline + adherence-focused texts + phone counselling vs varenicline alone

Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.2. Comparison 1: Behavioural support vs brief advice or no intervention, Outcome 2: Quit attempts

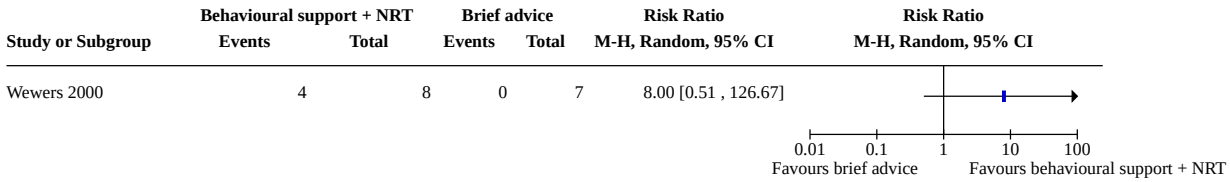


Study or Subgroup	Behavioural support Events	Total	Brief advice Events	Total	Risk Ratio M-H, Random, 95% CI
Shuter 2022	67	255	44	251	1.50 [1.07 , 2.10]

Comparison 2. Behavioural support + NRT vs brief advice

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Tobacco use cessation	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

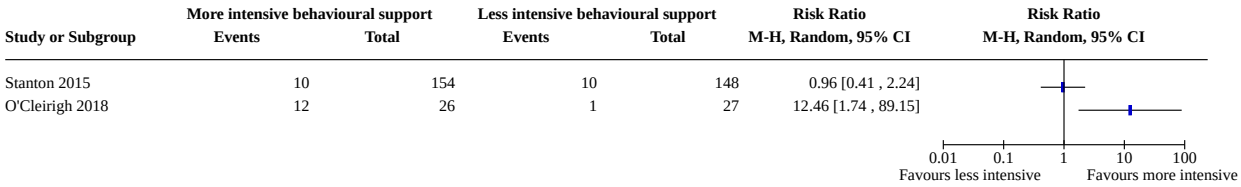
Analysis 2.1. Comparison 2: Behavioural support + NRT vs brief advice, Outcome 1: Tobacco use cessation



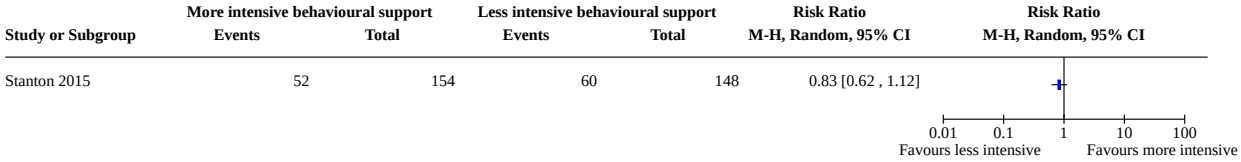
Comparison 3. Behavioural support vs a different type of behavioural support

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Tobacco use cessation	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
3.2 Quit attempts	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

Analysis 3.1. Comparison 3: Behavioural support vs a different type of behavioural support, Outcome 1: Tobacco use cessation



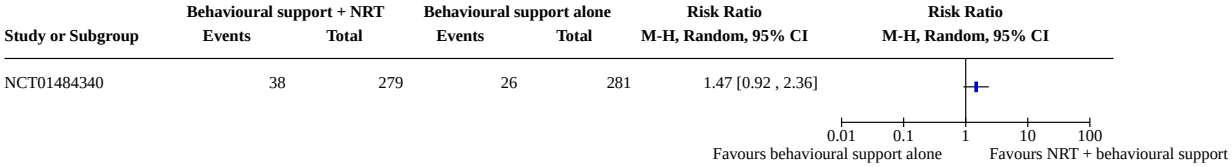
Analysis 3.2. Comparison 3: Behavioural support vs a different type of behavioural support, Outcome 2: Quit attempts



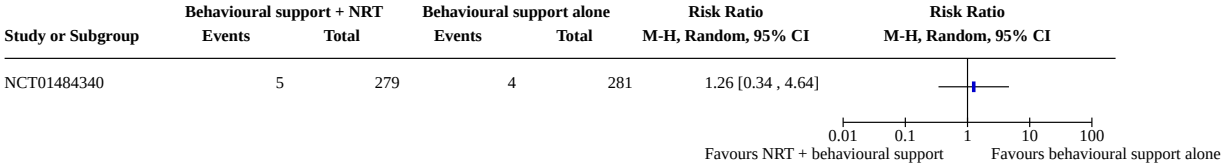
Comparison 4. Behavioural support + NRT vs behavioural support alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Tobacco use cessation	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
4.2 Serious adverse events	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
4.3 All-cause mortality	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

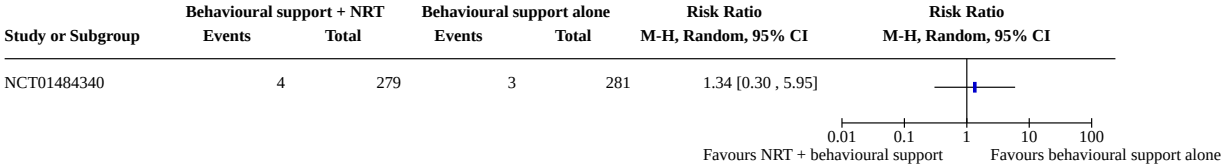
Analysis 4.1. Comparison 4: Behavioural support + NRT vs behavioural support alone, Outcome 1: Tobacco use cessation



Analysis 4.2. Comparison 4: Behavioural support + NRT vs behavioural support alone, Outcome 2: Serious adverse events



Analysis 4.3. Comparison 4: Behavioural support + NRT vs behavioural support alone, Outcome 3: All-cause mortality



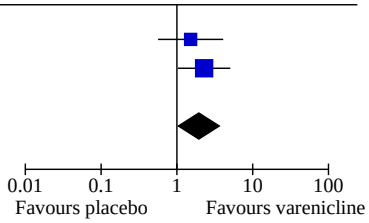
Comparison 5. Varenicline vs placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Tobacco use cessation	2	427	Risk Ratio (M-H, Random, 95% CI)	1.95 [1.05, 3.62]
5.2 Adverse events	2	427	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.60, 1.33]
5.3 Serious adverse events	2	427	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.58, 2.22]

Analysis 5.1. Comparison 5: Varenicline vs placebo, Outcome 1: Tobacco use cessation

Study or Subgroup	Varenicline Events	Total	Placebo Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Ashare 2019	9	89	6	90	39.2%	1.52 [0.56 , 4.08]
Mercie 2018	18	123	8	125	60.8%	2.29 [1.03 , 5.06]
Total (95% CI)		**212**		**215**	**100.0%**	**1.95 [1.05 , 3.62]**
Total events:	27		14			

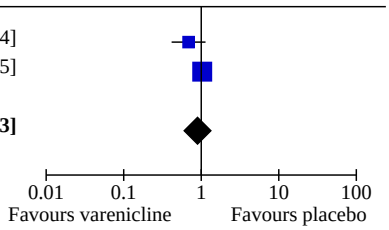
Heterogeneity: Tau² = 0.00; Chi² = 0.40, df = 1 (P = 0.53); I² = 0%
Test for overall effect: Z = 2.11 (P = 0.04)
Test for subgroup differences: Not applicable



Analysis 5.2. Comparison 5: Varenicline vs placebo, Outcome 2: Adverse events

Study or Subgroup	Varenicline Events	Total	Placebo Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Ashare 2019	19	89	28	90	34.3%	0.69 [0.41 , 1.14]
Mercie 2018	78	123	77	125	65.7%	1.03 [0.85 , 1.25]
Total (95% CI)		**212**		**215**	**100.0%**	**0.90 [0.60 , 1.33]**
Total events:	97		105			

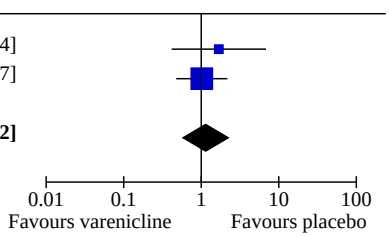
Heterogeneity: Tau² = 0.05; Chi² = 2.38, df = 1 (P = 0.12); I² = 58%
Test for overall effect: Z = 0.55 (P = 0.58)
Test for subgroup differences: Not applicable



Analysis 5.3. Comparison 5: Varenicline vs placebo, Outcome 3: Serious adverse events

Study or Subgroup	Varenicline Events	Total	Placebo Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Ashare 2019	5	89	3	90	22.8%	1.69 [0.42 , 6.84]
Mercie 2018	12	123	12	125	77.2%	1.02 [0.48 , 2.17]
Total (95% CI)		**212**		**215**	**100.0%**	**1.14 [0.58 , 2.22]**
Total events:	17		15			

Heterogeneity: Tau² = 0.00; Chi² = 0.39, df = 1 (P = 0.53); I² = 0%
Test for overall effect: Z = 0.38 (P = 0.70)
Test for subgroup differences: Not applicable

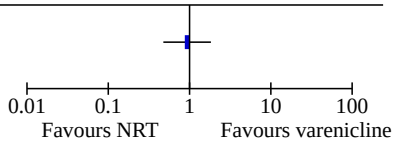


Comparison 6. Varenicline vs NRT

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Tobacco use cessation	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

Analysis 6.1. Comparison 6: Varenicline vs NRT, Outcome 1: Tobacco use cessation

Study or Subgroup	Varenicline Events	Varenicline Total	NRT Events	NRT Total	Risk Ratio M-H, Random, 95% CI
Tindle 2022	14	100	15	100	0.93 [0.48 , 1.83]

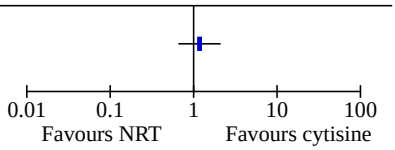


Comparison 7. Cytisine vs NRT

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 Tobacco use cessation	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

Analysis 7.1. Comparison 7: Cytisine vs NRT, Outcome 1: Tobacco use cessation

Study or Subgroup	Cytisine Events	Cytisine Total	NRT Events	NRT Total	Risk Ratio M-H, Random, 95% CI
Tindle 2022	20	100	17	100	1.18 [0.66 , 2.11]

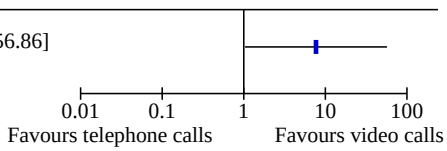


Comparison 8. Different modalities of support

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Tobacco use cessation	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

Analysis 8.1. Comparison 8: Different modalities of support, Outcome 1: Tobacco use cessation

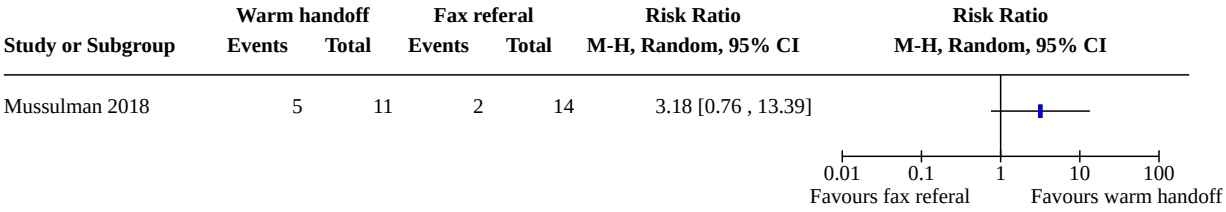
Study or Subgroup	Video calls Events	Video calls Total	Telephone calls Events	Telephone calls Total	Risk Ratio M-H, Random, 95% CI
Kim 2018	8	25	1	24	7.68 [1.04 , 56.86]



Comparison 9. System change interventions: warm handoff versus fax referral

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 Tobacco use cessation	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

Analysis 9.1. Comparison 9: System change interventions: warm handoff versus fax referral, Outcome 1: Tobacco use cessation



ADDITIONAL TABLES

Table 1. Risk of bias in non-randomised studies

Study	Bias due to confounding	Bias in selection of participants into study	Bias in classification of interventions	Bias due to deviation froms intended intervention	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported results	Overall risk of bias
Huber 2012	**Serious** (some important confounders, such as alcohol consumption, were only measured in a subset of participants and therefore were not included in the main analysis).	**Low** (all eligible patients at participating sites with relevant information were included in the analysis)	**Low** (intervention groups clearly defined and recorded)	**Low** (no deviations from the intended intervention beyond what would be expected in usual practice)	**Low** (high follow-up rates)	**Serious** (self-reported outcomes without biochemical validation)	**Low** (reported effect estimate not likely to be selected, on the basis of the results)	**Serious**

APPENDICES

Appendix 1. Search strategies

Cochrane Tobacco Addiction Group Specialised Register (via CRSWeb)

1. ("HIV/AIDS".):AB,EH,EMT,KW,KY,MH,TI,XKY
2. (HIV):AB,EH,EMT,KW,KY,MH,TI,XKY
3. (PLWHA):AB,EH,EMT,KW,KY,MH,TI,XKY
4. ("acquired immunodeficiency syndrome" or "acquired immunedeficiency syndrome" or "acquired immuno-deficiency syndrome" or "acquired immune-deficiency syndrome"):AB,EH,EMT,KW,KY,MH,TI,XKY
5. MESH DESCRIPTOR Infections EXPLODE ALL
6. MESH DESCRIPTOR Acquired Immunodeficiency Syndrome EXPLODE ALL
7. MESH DESCRIPTOR HIV
8. MESH DESCRIPTOR HIV-1
9. MESH DESCRIPTOR HIV-2
10. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9

CENTRAL (via CRSWeb)

1. ("HIV/AIDS".):AB,EH,EMT,KW,KY,MH,TI,XKY
2. (HIV):AB,EH,EMT,KW,KY,MH,TI,XKY
3. (PLWHA):AB,EH,EMT,KW,KY,MH,TI,XKY
4. ("acquired immunodeficiency syndrome" or "acquired immunedeficiency syndrome" or "acquired immuno-deficiency syndrome" or "acquired immune-deficiency syndrome"):AB,EH,EMT,KW,KY,MH,TI,XKY
5. MESH DESCRIPTOR Infections EXPLODE ALL
6. MESH DESCRIPTOR Acquired Immunodeficiency Syndrome EXPLODE ALL
7. MESH DESCRIPTOR HIV
8. MESH DESCRIPTOR HIV-1
9. MESH DESCRIPTOR HIV-2
10. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
11. MESH DESCRIPTOR Tobacco Use Disorder EXPLODE ALL
12. MESH DESCRIPTOR Tobacco Use Cessation EXPLODE ALL
13. MESH DESCRIPTOR Tobacco Smoke Pollution EXPLODE ALL
14. MESH DESCRIPTOR Tobacco Use Cessation Products EXPLODE ALL
15. MESH DESCRIPTOR Tobacco, Smokeless EXPLODE ALL
16. (SMOKING* or TOBACCO or TOBACCO-USE-DISORDER* or TOBACCO-SMOKELESS* or TOBACCO-SMOKE-POLLUTION* or TOBACCO-USE-CESSATION* or NICOTINE*):MH
17. (smoking cessation):MH
18 (SMOKING CESSATION or ANTISMOK*):TI,AB
19. (quit* or smok* or nonsmok* or cigar* or tobacco* or nicotine*):TI
20. MESH DESCRIPTOR Smoking Cessation EXPLODE ALL
21. #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20
22. #10 AND #22

MEDLINE and PsycINFO (via Ovid)

1. smoking cessation.mp. or exp Smoking Cessation/
2. tobacco cessation.mp. or "Tobacco-Use-Cessation"/
3. (nicotine dependence or tobacco dependence).mp.
4. exp Smoking/th [Therapy]
5. "Tobacco-Use-Disorder"/
6. Tobacco-Smokeless/
7. exp Tobacco-Smoke-Pollution/
8. Smoking reduction/ or Smoking reduction.mp.
9. Smoking prevention/
10. Vaping/ or vaping.mp.
11. Electronic Nicotine Delivery Systems/
12. electronic cigar*.mp.
13. exp Pipe smoking/ or exp Tobacco smoking/ or exp Tobacco Products/
14. ((quit$ or stop$ or ceas$ or giv$ or abstain* or abstinen*) adj5 (smoking or smoke* or tobacco)).ti,ab.
15. exp Tobacco/ or exp Nicotine/
16. OR/1-15

17. exp hiv infections/ or exp acquired immunodeficiency syndrome/
18. hiv/ or hiv-1/ or hiv-2/
19. ("acquired immunodeficiency syndrome" or "acquired immunedeficiency syndrome" or "acquired immuno-deficiency syndrome" or "acquired immune-deficiency syndrome").mp.
20. "HIV/AIDS".mp.
21. HIV.mp.
22. PLWHA.mp
23. or/17-22
24. 16 AND 23

Embase (via Ovid)

1. smoking cessation.mp. or exp Smoking Cessation/
2. tobacco cessation.mp. or "Tobacco-Use-Cessation"/
3. (nicotine dependence or tobacco dependence).mp.
4. exp Smoking/th [Therapy]
5. "Tobacco-Use-Disorder"/
6. Tobacco-Smokeless/
7. exp Tobacco-Smoke-Pollution/
8. Smoking reduction/ or Smoking reduction.mp.
9. Smoking prevention/
10. Vaping/ or vaping.mp.
11. Electronic Nicotine Delivery Systems/
12. electronic cigar*.mp.
13. exp *Pipe smoking/ or exp *Tobacco smoking/ or exp *Tobacco Products/
14. ((quit$ or stop$ or ceas$ or giv$ or abstain* or abstinen*) adj5 (smoking or smoke* or tobacco)).ti,ab.
15. exp Tobacco/ or exp Nicotine/
16. OR/1-15
17. exp hiv infections/ or exp acquired immunodeficiency syndrome/
18. hiv/ or hiv-1/ or hiv-2/
19. ("acquired immunodeficiency syndrome" or "acquired immunedeficiency syndrome" or "acquired immuno-deficiency syndrome" or "acquired immune-deficiency syndrome").mp.
20. "HIV/AIDS".mp.
21. HIV.mp.
22. PLWHA.mp
23. or/17-22
24. 16 AND 23

WHAT'S NEW

Date	Event	Description
5 August 2024	New search has been performed	Updated with updated methods and a new search on 01 December 2022. New searches found 11 new studies
5 August 2024	New citation required and conclusions have changed	The previous review concluded that the evidence suggested that combined tobacco cessation interventions provide similar outcomes to controls in people living with HIV in the long term. For the current review, this is true for the following comparisons: behavioural support versus brief advice, one type of behavioural support versus another, behavioural support plus nicotine replacement therapy (NRT) versus behavioural support alone/brief advice, varenicline versus NRT, and cytisine versus NRT. However, the current review concludes that varenicline likely helps people living with HIV to quit smoking for six months or more when compared to a placebo control. From the current review, there is also no clear evidence to support or refute the use of system-change interventions in order to increase tobacco use cessation or receipt of cessation interventions among people living with HIV who use tobacco.

HISTORY

Protocol first published: Issue 5, 2014
Review first published: Issue 6, 2016

CONTRIBUTIONS OF AUTHORS

Noreen Mdege (NDM) conceived the update to the original review and is the guarantor of the content. NDM led the design of, and co-ordinated the review update. Sarwat Shah (SS) and NDM wrote the protocol with input from Kamran Siddiqi (KS), Omara Dogar (OD), Jonathan Livingstone-Banks (JL-B), Erica Pool (EP) and Peter Weatherburn (PW). JL-B searched for the studies for inclusion in the review. NDM, SS, OD and JL-B screened the reports and agreed on inclusion of the studies. NDM, SS, OD, JL-B and Cosmas Zyambo (CZ) extracted data. NDM, SS, OD and JL-B conducted the assessment of the risk of bias in the included studies. NDM and JL-B undertook the analysis and conducted the assessment of the certainty in the body of evidence. NDM, SS, KS, OD, JL-B, EP and PW contributed to the interpretation of data. NDM drafted the text. NDM and JL-B oversaw the review process. All authors reviewed the text and are responsible for the analyses and conclusions.

DECLARATIONS OF INTEREST

Noreen Mdege (NDM) has published on tobacco use and cessation among people living with HIV, but was not involved in any of the studies included in this review. NDM is a non-practising registered pharmacist.

Sarwat Shah (SS) is a medical doctor practising in the UK. SS has published on tobacco use and cessation among people living with HIV, but was not involved in any of the studies included in this review.

Omara Dogar (OD) is a non-practicing medical doctor. OD has published on tobacco use and cessation among people living with HIV, but was not involved in any of the studies included in this review.

Erica Pool (EP) works as an HIV and sexual health doctor at Mortimer Market Centre, UK.

Peter Weatherburn (PW) has no conflicts of interest to declare.

Kamran Siddiqi (KS) is a Professor in Global Public Health at the University of York and Director of an NIHR (National Institute for Health Research)-funded Group that is to address smokeless tobacco. KS has published on tobacco use and cessation among people living with HIV, but was not involved in any of the studies included in this review. KS has received a research grant (GRAND 2014) from Pfizer, a pharmaceutical company that makes drugs for tobacco cessation, and from the National Institute for Health Research (NIHR) for the ASTRA (Addressing Smokeless Tobacco and Building Research Capacity in South Asia) Cessation study, which may be included in future updates of this review.

Cosmas Zyambo (CZ) is a medical doctor who has published on tobacco use and cessation among people living with HIV, including an unfunded review on the topic, but was not involved in any of the studies included in this review.

Jonathan Livingston-Banks (JL-B) was the Managing Editor of the Cochrane Tobacco Addiction Group and is now an Associate Editor for Cochrane. He played no role in the editorial process for this review.

SOURCES OF SUPPORT

Internal sources

- Institute for Global Health, University College London, UK

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- University of York, UK

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- Sigma Research, Department of Public Health, Environments & Society, London School of Hygiene and Tropical Medicine, London, UK

  Employer of PW
- Department of Community and Family Medicine, School of Public Health, The University of Zambia, Zambia

  Employer of CZ
- Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

  Employers of JL-B
- NIHR Doctoral Research Fellowship, UK

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External sources

- No external source of support, Other

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Differences between this update and the original protocol and review:

- We edited the title from "Interventions for tobacco use cessation in people living with HIV and AIDS" to just "Interventions for tobacco use cessation in people living with HIV" to be consistent with advancements in the terminology used for this population in the field. We also use "people living with HIV (PLWH)" and not "people living with HIV and AIDS (PLWHA)" throughout the review.
- Change in authors. New authors: Noreen Dadirai Mdege, Cosmas Zyambo and Jonathan Livingstone-Banks joined the review team; and previous author Ryan Lindsay did not contribute to this version of the review.
- We removed one of the secondary objectives in the protocol and original review: "to assess whether interventions combining pharmacotherapy and behavioural support are more effective than either type of support alone in PLWH." This was due to the fact that we were generally interested in any comparisons, so this comparison would automatically be investigated in the review if such studies were identified.
- We could not compare the benefits and harms of individual-/group-level and system-change interventions for tobacco cessation that are tailored to the needs of PLWH with that of non-tailored cessation interventions because the majority of the interventions were tailored.
- For types of studies, we added the exclusion of cross-over studies because of the types of interventions used, outcomes investigated and the possibility of problematic carry-over effects.
- We added the following secondary outcomes.
  - Quit attempts/quit episodes. This was because of the inclusion of tobacco cessation induction studies designed to increase quit attempts and/or cessation among participants who are not yet ready to quit.
  - The proportion of patients who are smokers at the time of a consultation who receive a tobacco cessation intervention. This was because this is an important outcome for system-change interventions.
  - Quality of life. We judged this as an important outcome for PLWH considering the potential impact of the illness on quality of life.
- We removed the preplanned searches of the US National Institutes of Health registry at www.clinicaltrials.gov, the World Health Organization (WHO) trials registry platform at apps.who.int/ trialsearch/, the European Union (EU) clinical trials register at www.clinicaltrialsregister.eu, and the Pan African Clinical Trials Registry at www.pactr.org. This was because, by searching CENTRAL, we were able to identify studies registered in those registries.
- We removed the preplanned searches of: theses and dissertations via EThOS and ProQuest; conference abstracts via the Conference Proceedings database in Web of Science; and handsearching of databases of the Society for Research on Nicotine and Tobacco, International AIDS Conference and British HIV Association. Any relevant studies in these sources would be identified through the databases that we included.
- We added methods to manage unit of analysis issues in cluster-RCTs in order to account for unit of analysis errors for those cluster-RCTs where the unit of analysis was individual participants but clustering of individuals in the data was not considered in the analysis.
- For our meta-analyses, we added a plan to conduct further investigations e.g. through subgroup analyses where heterogeneity was more than 75%, if the data allowed.
- We did not conduct the preplanned investigation of publication bias for the primary outcome of long-term cessation for all study groupings using funnel plot with pseudo-95% confidence limits. This was because there were not enough studies: we identified fewer than 10 studies for each of the analyses.
- We handled data synthesis for adverse events as for the other outcomes, that is, based on numbers randomised to an intervention or control group and using intention-to-treat where possible. Where this was not possible, we clearly indicate how the analysis was carried out. For example, where we simply report the results as they were reported in the paper due to inadequate information to allow our intended analysis. We considered all adverse events (including serious adverse events (SAEs)) reported up to the last follow-up. We did not limit the analysis to SAE, or conduct sensitivity analyses restricting the denominator to those known to have taken at least one dose of treatment/intervention, as per the original protocol and review. This was consistent with other analyses in the review.
- We removed the preplanned subgroup analyses by provider, model of contact, whether participants were selected because of their willingness and/or motivation to quit or not, and total intervention contact time. Research suggests that these variables do not make a significant difference to intervention benefits/harms. Instead, we planned to conduct the subgroup analyses listed below, although they were not performed due to not having enough studies in the meta-analyses.
  - For individual-/group-level interventions, we planned to explore the effects of the following:

- number of intervention sessions: 1 to 3 sessions; 4 to 8 sessions and more than 8 sessions. There is evidence to suggest there is an impact on intervention benefits/harms; and
- type of tobacco product, which has not been investigated before.

- For system-change interventions, we planned to explore the effects of the level of intervention, that is, structural-/organisational-level intervention (policy-/management-level change) versus provider-/delivery-level intervention (training/skills/capacity). This has not been investigated before.

- We removed the preplanned sensitivity analysis to test for small-study effects. Instead, we planned to test the effects of removing studies at high risk of bias. However, we could not do so because of the small number of studies within each of the analyses.

INDEX TERMS

Medical Subject Headings (MeSH)

*Acquired Immunodeficiency Syndrome; Behavior Therapy [methods]; *HIV Infections; Nicotinic Agonists [therapeutic use]; Randomized Controlled Trials as Topic; Smoking Cessation [methods]; Time Factors; Tobacco Use Cessation [*methods]; Varenicline [therapeutic use]

MeSH check words

Humans